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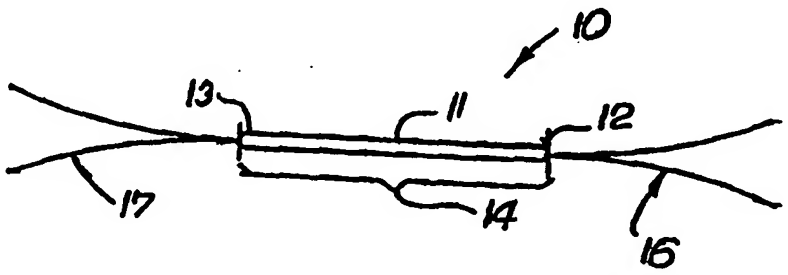

(57) Abstract

Artificial chordae having a strand member and a first and second pair of sutures at either longitudinal end of the strand member. The artificial chordae is preferably a unitary unit, formed from inelastic flexible material. In one embodiment, the artificial chordae comprises multiple strand members joined together at a joined end. Different sized artificial chordae are provided sized to fit the patient's heart. The appropriately sized artificial chordae is chosen by using a chordae sizing gauge having a shaft and a transverse member, to measure the space within the patient's heart where the artificial chordae is attached.

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ARTIFICIAL CHORDAE REPLACEMENT

BACKGROUND OF THE INVENTION

This application is a continuation-in-part application of prior co-pending application U.S. Serial No. 08/923,892, filed September 4, 1997, entitled Artificial Chordae Replacement.

This invention relates to an artificial chordae device, and more particularly to an artificial chordae replacement for a mitral or tricuspid valve.

A vertebrate heart consists of four cavities, known as the left and right atria and the left and right ventricles. Oxygenated blood from the lungs is received by the left atrium, and passes into the left ventricle which forces it via the aorta to the tissues of the body. Blood returning from the body tissues is received by the right atrium, and passes into the right ventricle which forces it to the lungs to be oxygenated. A valve, known as the mitral or bicuspid valve, regulates the flow of blood between the left atrium and ventricle, whereas the tricuspid valve serves the same function for the right atrium and ventricle. The mitral valve is a thin continuous membrane having two indentations dividing it into two principal trapezoidal leaflets of unequal size. Tendinous strands known as chordae tendineae connect the edges of the valve leaflets to the papillary muscle on the ventricular surface, so that relaxation and contraction of the left ventricle will act on the mitral valve causing it to open and close. Furthermore, the subvalvular structures, e.g. the papillary muscles and chordae tendineae, play an important role in structuring the geometry of the heart and ventricular function.

Heart valve replacement is a well known procedure in which an artificial heart valve prostheses is implanted in place of a diseased or malfunctioning heart valve. While artificial mechanical, man made, valves

are generally durable, the patient may be prone to infection and must be treated with anticoagulant medications for the rest of their lives to prevent thromboembolic complications or thrombotic occlusion of the prosthesis. Moreover, anticoagulation therapy may cause life threatening complications, and is responsible for a high percentage of lethal and nonlethal heart valve complications. The need for anticoagulation therapy can be avoided in general by the use of artificial biological heart valves, such as bovine xenografts. Nevertheless, dystrophic calcification with subsequent degeneration is the major cause of failure of such bioprostheses in the long term, and bioprosthetic valve dysfunction may cause precipitous clinical deterioration requiring reoperation in a high percentage of patients. Additionally, when mitral or tricuspid valve replacement is performed, the chordae are cut, thus leaving the geometry and function of the ventricle impaired and in need of reconstruction.

As an alternative to conventional heart valve replacement operations, a high percentage of patients could be treated with repair including the repair of diseased and malfunctioning heart valve tendineae chordae. Such reconstructive heart valve operations generally don't require anticoagulation therapy, and the patient's can expect a significantly reduced risk of postoperative complication with a subsequently higher life expectancy. However, heart valve tendineae chordae repair operations are technically demanding. In general, the present way of replacing a chordae uses a simple suture with one needle on each end of the suture. The suture is stitched through the papillary muscle and secured thereto with a knot. The two ends of the suture are then similarly stitched through the free ends of the valve leaflets. However, in attempting to tie a second knot to secure the suture to the valve leaflets, because there is nothing holding the suture in place, the length of the suture spanning the distance between the papillary muscle

and valve leaflet is likely to change. This complication increases the skill and time required to perform the procedure. Moreover, the valve will not function properly if the length of the artificial chordae between the papillary muscle and valve leaflet is overly long or overly short.

Therefore, what has been needed is an artificial chordae replacement for the mitral and tricuspid valves which is easily secured in place between the papillary muscle and valve leaflet, and which will not allow for a change of length during the attachment process. Additionally, a need exists for easy and secure reconstruction of the subvalvular structures during valve replacement. The present invention satisfies these and other needs.

SUMMARY OF THE INVENTION

The invention is directed to an artificial heart valve chordae, a heart valve chordae sizing gauge, and a method of using both to replace chordae in a heart valve. The artificial chordae of the invention is suitable for use in both the mitral and tricuspid heart valves.

The artificial heart valve chordae of the invention generally comprises a strand member with two sutures on each end of the member. One pair of sutures is used to attach the first end of the strand to the papillary muscle while the other pair of sutures attaches the second end to the edge of the valve leaflets. In one embodiment, an artificial chordae having one end for attachment to the papillary muscle (or valve leaflet) and multiple ends for attachment to multiple locations on the valve leaflets (or papillary muscle) is provided by an artificial chordae comprising at least two strand members side by side, or longitudinally juxtaposed, and joined together at one end. At the end where the strands are joined together is one pair of sutures for attaching that end to the papillary muscle (or valve leaflet), and at the free end of each strand is a pair of

sutures for attaching that free end to a separate location on the valve leaflet (or papillary muscle).

The artificial chordae are formed from inelastic flexible material that is bioincorporable, such as TEFLON® (expanded polytetrafluoroethylene), or other suitable materials. A presently preferred embodiment has the strand member and sutures formed as a unitary one piece unit, which minimizes the risk of a rupture forming in the artificial chordae during use.

Once the artificial chordae is sutured into place, the length of the strand member defines the length of the implanted artificial chordae. The artificial chordae of the invention come in a variety of preset sizes with strand members having different fixed lengths, so that an artificial chordae can be chosen which has a length that is approximately equal to the distance between the site of implantation of the papillary muscle and valve leaflet where the artificial chordae will be attached. This configuration, having a strand member that is a fixed length sized to fit the patient's heart with suture pairs at each end of the member, is a substantial advance. The configuration provides for easy attachment and prevents a disadvantageous change in the artificial chordae length during attachment.

Because the artificial chordae is sized to fit the patient's heart, the distance between the patient's papillary muscle and valve leaflet is measured in order to select the appropriately sized artificial chordae. One aspect of the invention provides a heart valve chordae sizing gauge used to measure the distance between the papillary muscle and valve leaflet where the artificial chordae will be attached. The sizing gauge generally comprises a shaft with a transverse member, or tab. By holding the sizing gauge between the papillary muscle and valve leaflet at the desired location of the artificial chordae, the distance between the transverse

member and one end of the shaft is used to approximate the length of the artificial chordae which is required. The transverse member is fixed to the shaft, so the sizing gauge is provided in a variety of different sizes in which the distance between the transverse member and the ends of the shaft vary.

In making the measurement, the physician is likely to try more than one differently sized sizing gauge until a gauge is found in which the distance between the transverse member and one end of the shaft is approximately equal to the distance between the papillary muscle and valve leaflet edge. Moreover because the distance between the papillary muscle and valve leaflet edge is not uniform, the physician measures the maximum and minimum distance so that an artificial chordae is chosen having a length that is between that maximum and minimum distance. In an alternative embodiment, the transverse member is slidably mounted on the shaft, to allow for adjustment of the distance between the transverse member and the end of the shaft during measurement.

In the surgical operation, the distance between the papillary muscle and the edge of the valve leaflet is measured with the heart valve chordae sizing gauge of the invention. Then, an artificial chordae having the appropriate strand length is chosen and attached in place using the pairs of sutures. One pair of sutures is threaded through the papillary muscle and tied into a knot, while a similar procedure is performed at the valve leaflet with the pair of sutures on the opposite end of the strand member. An identical procedure is used for the artificial chordae embodiment of the invention having multiple strand members joined together, except that a separate pair of sutures must be attached to the heart tissue for the free end of each strand member.

An identical procedure is performed in the case of valve replacement, except that one pair of sutures is placed through the valve

annulus of the heart valve prosthesis before implanting the heart valve prosthesis, and then the second pair of sutures is attached to the papillary muscle.

The artificial chordae of the invention has superior ease of attachment due to the pair of sutures on each end of the strand member, so that the strand member defines the fixed length of the implanted artificial chordae. The invention thus avoids a change in the length of the artificial chordae during attachment, and therefore the risk of an improperly sized and possibly inoperative artificial chordae being attached. Furthermore, in the case of mitral or tricuspid valve replacement, the artificial chordae of the invention allows for easy and secure reconstruction of the subvalvular structures. These and other advantages of the invention will become more apparent from the following detailed description of the invention and the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 illustrates a conventional artificial chordae of the prior art.

Fig. 2 is an elevational view of an artificial chordae which embodies features of the invention.

Fig. 3 is an elevational view of one embodiment of an artificial chordae having multiple strand members.

Fig. 4 is an elevational view of a sizing gauge of the invention.

Fig. 5 illustrates a sizing gauge of the invention in use, positioned between a papillary muscle and a valve leaflet edge.

Fig. 6 is a schematic sectional view of a human heart.

Fig. 7 is an enlarged sectional view of the mitral valve of a human heart.

Figs. 8a and 8b illustrate a sequence of steps in the attachment of the prior art artificial chordae.

Figs. 9a and 9b illustrate a sequence of steps in the attachment of an artificial chordae of the invention.

Fig. 10 illustrates an artificial heart valve prosthesis.

Fig. 11 is an elevational view of an artificial chordae which embodies features of the invention having a pledget at one end of each pair of sutures.

Fig. 12 is an elevational view of one embodiment of an artificial chordae having multiple strand members and having a pledget at one end of each pair of sutures.

Figs. 13a-13c illustrate one embodiment in which the strand member is folded.

Fig. 14 illustrates the folded strand member shown in Fig. 13c having a pin connecting the folds together.

Fig. 15 illustrates the folded strand member shown in Fig. 13c having a ring connecting the folds together.

Fig. 16 illustrates the folded strand member shown in Fig. 13c having a clip connecting the folds together.

Fig. 17 illustrates an artificial chordae assembly which embodies features of the invention being attached to a patient's mitral valve leaflet and papillary muscle, and having a stopping member comprising a clip on the second pair of sutures.

Fig. 18 illustrates an alternative embodiment of an artificial chordae assembly which embodies features of the invention, having a stopping member comprising a securable tube on the second pair of sutures.

Fig. 19 illustrates an alternative embodiment of an artificial chordae which embodies features of the invention having a suture and stopping members thereon and being attached to a patient's mitral valve leaflet and papillary muscle.

DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 illustrates a conventional chordae replacement suture 1 of the prior art, and needles 2a, b attached to the end of each suture.

The artificial heart valve chordae 10 of the invention is illustrated in Fig. 2, and comprises at least one strand member 11 having a first end 12 and a second end 13, and a longitudinal portion 14. A first pair of sutures 16 extends from the strand member first end 12, and a second pair of sutures 17 extends from the strand member second end 13. One embodiment of the invention having multiple strand members 11 is illustrated in Fig. 3, and comprises at least two strand members 11 having a joined end 18. The strand member first ends 12 are fixed together to form the joined end 18, and the strand members 11 are longitudinally juxtaposed so that the strand longitudinal portions 14 are adjacent one another. One pair of sutures 19 extend from the joined end 18, and pairs of sutures 20 extend from the second end of each strand member. The strand members 11 joined together may have different longitudinal lengths, or may have substantially equal lengths.

For attaching the artificial chordae 10 to the patient's heart tissue, the end of each suture 16 would be provided with needles (not shown). The sutures 16, which may be from about 75 cm to about 90 cm in length, typically about 75 cm, may be surgically attached in the heart to attach the artificial chordae. The artificial chordae 10 is provided in different sizes having strand members 11 of various lengths. It is the size of the strand member 11 which defines the length of the implanted artificial chordae in place in the patient's heart. The strand member 11 is configured to extend from the papillary muscle to a location on the heart valve, and may be about 1 cm to about 6 cm in length, depending on the size of the heart as well as the point of placement chosen by the surgeon.

The strand member 11 has a diameter of about 0.1 mm to about 0.25 mm, typically about 0.15 mm.

In a presently preferred embodiment, the strand member 11 and sutures 16, 17 of the artificial chordae are formed from a unitary unit. However, the strand and sutures may be formed as separate units joined together, and possibly from different materials. The artificial chordae is formed from biocompatible material that is relatively inelastic and flexible, to allow easy movement of the valve leaflets during opening and closing of the valve. The presently preferred material is TEFLON®, or expanded polytetrafluoroethylene, although it would be obvious to one skilled in the art that there are other suitable materials, including those which are frequently used to form sutures. The expanded polytetrafluoroethylene may be suture material or fabric material.

One aspect of the invention provides a heart valve chordae sizing gauge 21 for measuring the distance between the papillary muscle 38 and the valve leaflet edge 37. The sizing gauge 21 is illustrated in Fig. 4, and comprises a shaft 22 having a first end 23, a second end 24, and a transverse member 26 spaced a distance between the shaft first and second ends. The transverse member 26 is fixed to the shaft, and the sizing gauge 21 is provided in different sizes which correspond to the different sized artificial chordae 10. The size of the sizing gauge 21 is defined by the distance between the transverse member 26 and the shaft ends 23, 24. The sizing gauge 21 is formed from biocompatible material, and is preferably formed from a plastic material.

An alternative embodiment provides the transverse member 26 slidably mounted so as to slide along the shaft 22, so that the size of the sizing gauge 21 can be adjusted during the measurement. A means to releasably lock the slidable transverse member 26 onto the rod is provided. In the embodiment shown in Fig. 4, frictional engagement is

used to lock the slidable transverse member onto the rod, although there are a variety of suitable locking mechanisms, including a compression fit clamp, screw clamp, and the like.

When the size of the artificial chordae is to be chosen, the physician measures the maximum and minimum distance between the papillary muscle 38 and valve leaflet edge 37, in order to choose an artificial chordae 10 with the correct size that is somewhere between the maximum and minimum lengths measured.

To make the measurements, the physician positions the sizing gauge 21 in place between the papillary muscle 38 and valve leaflet edge 37 (Fig. 5). The distance between the muscle 38 and leaflet edge 37 is then compared to the distance between the transverse member 26 and the shaft end, preferably the shaft second end 24. If necessary, the sizing gauge is exchanged for a sizing gauge of a different size until the distance between the muscle 38 and leaflet edge 37 is approximately equal to the distance between the transverse member 26 and the shaft second end 24.

The human heart 30 is illustrated in Fig. 6, and includes the left and right atria 31, 32, and the left and right ventricle 33, 34. The mitral valve 35 is between the left atrium 31 and left ventricle 33, and the tricuspid valve 36 is similarly located between the right atrium 32 and right ventricle 34. In the mitral valve 35, the edges of the mitral valve leaflets 37 are connected to the papillary muscle 38 by the chordae tendineae 39 (Fig. 7).

Fig. 8 illustrates a sequence of steps used in attaching the prior art suture 1 in place in the heart. The suture 1 is attached in place by passing needles 2a, b through the papillary muscle 38 (Fig. 8a) and then tied into a knot 3. The needles 2a, b are then passed through the edge of the valve leaflet 37 (Fig. 8b), at which point a second knot is tied to secure the suture 1 in place.

Fig. 9 illustrates a series of steps used to attach the artificial chordae 10 of the invention, where the suture 16 is passed through the papillary muscle 38 secured in place with knot 46 (Fig. 9a), and suture 17 is passed through the valve leaflet edge and secured in place with knot 47 (Fig. 9b).

The method of replacing a chordae in a heart valve of a patient using the artificial chordae 10 of the invention comprises measuring the distance between the papillary muscle 38 and valve leaflet edge 37 using a heart valve chordae sizing gauge 21. As discussed above, the physician may measure a maximum and minimum distance between the papillary muscle 38 and valve leaflet edge 37, and calculate an average distance. An appropriately sized artificial chordae 10 is then chosen, which is surgically attached to the papillary muscle 38 and valve leaflet edge 37 at locations on the heart tissue corresponding to the location of the chordae being replaced. The first pair of sutures 16 is stitched through the papillary muscle 38 (or valve leaflet edge 37) and the sutures 16 are tied into a knot 46 so that the strand member first end 12 is secured to the papillary muscle 38 (or valve leaflet edge 37). The second pair of sutures 17 are then stitched though valve leaflet edge 37 and tied into a knot 47 to secure the strand member second end 13 to the valve leaflet edge 37.

An identical procedure is performed in the case of heart valve replacement, except that one pair of artificial chordae sutures 16,17 is

attached to the valve annulus 51 of the artificial heart valve prosthesis 50 before implanting the prosthesis 50, and then the other pair of artificial chordae sutures 16,17 is attached to the original or replacement papillary muscle after the artificial heart valve prosthesis 50 is implanted. The sutures may be pledget-supported with at least one patch 52 as illustrated in Figs. 11 and 12. The pledget may be fixedly attached to the artificial chordae strand member or sutures, or alternatively, slidably attached thereto, to facilitate positioning or suturing thereof.

In an alternative embodiment, the strand member 11 has a length that is adjustable, so that the size of the artificial chordae can be adjusted. The length may be adjusted *in situ*. The chordae may be fashioned as described above with one suture at each end or a plurality of sutures at each end. The chordae strand member may have a variety of configurations including tubular (cylindrical), prismatic, bifurcated, multi-subunited with multiple ends, flat sheet with single or multiple segmented end tethers and the like. The chordae strand member may be formed of a variety of materials that may be length adjusted in situ. A variety of mechanisms may be utilized for length adjustment including, but not limited to, mechanical, chemical curing, heat curing, ultrasonic curing, and the like. For mechanical length adjustment, the chordae may be made of synthetic or natural polymers or noncorrosive metal, such as flexible surgical stainless steel. The materials may be formed into tubular fibrous elements that may be either singular or woven or braided to make up the strand member. In a presently preferred embodiment, the polymers include polyethylene, polypropylne, PET, PTFE, elastin, collagen, non-immunogenic silk, spider silk, and the like. To mechanically shorten the chordae one either end, or both ends, are attached to the papillary muscle and the valve ring, the strand member will be adjusted to the clinically appropriate length arrived at by a measurement device as described , echo

data, or clinical judgment. The chordae may be mechanically shortened as illustrated in Figs. 13a-13c. The chordae may be folded over, singly or multiply, pleating or embricating the chordae. The appropriate length chordae may be then fixed at the length via a central suture, piercing pin (1b), encircling loop or ring (1c), clasplike fastener or other securing device (1d).

Further the device may be mechanically shortened by a central take-up spool like device placed over the chordae allowing shortening from either end. This device may be manually wound-up or have a central sping to apply shortening tension. This device may be composed of hemocompatabile polymeric components or stainless steel or other non-corrosive elements (1e).

To chemically shorten the chordae it is envisioned that the central member will be made of a polymeric material amenable to chemical shrinkage. Natural polymers such as polyamino acid materials, proteins, i.e. collagen, rubbers, etc. or other synthetic materials amenable to chemical shrinkage may be utilized.

One embodiment will be to expose the central member utilizing an encircling, enveloping tubular device that circulates a shrinking agent over the in situ chordae to allow shrinkage. Care would be exerted with this method to prevent leakage into the field of the curing agent. Once cured the encircling curing sleeve would rinse the chordae with physiologically appropriate solvents to allow blood and field re-exposure.

A second embodiment would place a tubular device over the chordae which provides shortening tension on both ends yet allows the central member to be exposed to a solvent. For example, a chordae is made of an aliphatic polyester that dissolves in methylene chloride or other like solvent. The central component of the central member may then be reconfigured and "shrunk" via the compaction of the encircling

deice while the chordae is in a fluent state. Once at the right length the fluence of the central component may be reversed via vacuum evacuation of the solvent. Once adequate structural stability of the central member is established the encircling shrinkage device may be removed. The net result is that the chordae has been in situ remolded to a shorter but stubbier configuration.

To thermally shorten the chordae it is envisioned that the chordae may be composed of materials that eitther shrink when exposed to heat or may be remolded, i.e. similar to above though without the solvent. Heat sensitive materials include synthetic and natural polymers. To perform the in situ reconfiguration it is envisioned that an enveloping tubular member will be placed over the chordae and uniformly heated within its core. The chorde will then shrink. Materials that change from non-fluent to fluent state the device, similar to above, will have a tensioning mechanism favoring shrinkage while maintaining the central generally tubular structure of the chordae, i.e. it will act as a mold. Once reconfigured and cooled the device will be removed.

A typical chemical or thermal shrinkage device (70) for the artificial chordae is depicted in fig 14. The device is generally tubular to allow in situ enveloping of the chordae (1b). The device may have a single or plurality of electrical or hollow fluid conduits (71) to allow either electrical activation of a central heating element (72). Alternatively 72 may be a single or series of channels which in the closed configuration of the device (70) allows solvent or curing fluid perfusion or superfusion. Further the device may contain a central ultrasonic element, activated either peripherally or centrally to ultrasonically and/or thermally actuate the chordae. The device may be hinged (as in fig 14b) so that it may open and close around the chordae.

An example of an actual instrument is envisioned in fig 15. A surgically and ergonomically acceptable handle (1a) will be attached via a central member (1b) to the shrinkage member (1c). The shrinkage member will be central between two tethering spring-like tensioning elements (1d). These elements will tend to shorten the chordae when the central aspect of the chordae is subjected to chemical, thermal or ultrasonic energy allowing the material to creep under applied tension. While one configuration is shown it is clear that the tensioning element may be on only one end or both. The tensioning may be variable. A strain gauge or other measuring element may be incorporated to measure either the stress or the strain of the chordae so as to allow appropriate creep and reconfiguration and avoid tensile rupture of the chordae.

Thermosensitive and thermoplastic polymers may be utilized for the chordae. For example a material made of a nondegradable polymer composite with polycaprolactone would allow melting at 50 - 70°C. Further other thermoplastics i.e. polypropylene or polyethylene may be used and melted and recongigured in situ.

A device for changing the size of the chordae, as illustrated in Figs. 14a-14c includes an enveloping member, a tensioning member, and a measuring device. A method of adjusting the size of the chordae comprises grasping the chordae, encircling the chordae with the tubular member, tensioning the chordae or acuating it, as by changing from nonfluent to fluent states, to reduce the size of the chordae, deactivating the chordae to make it biocompatable, and releasing the chordae, as illustrated in Figs. 14a-14c.

Thus the length of the strand member is adjusted to correspond to the distance between the location on the papillary muscle and the location on the valve leaflet at which the ends of the strand member are attached. In one embodiment, the strand member is foldable,

and the length of the strand member is adjusted by folding the strand member one or more times, as illustrated in Figs. 13a, 13b, and 13c. Fig. 13b illustrates the strand member folded one time to decrease the length thereof, and Fig. 13c illustrates the strand member folded two times to further decrease the strand member length. The folds of the strand member are connected together to fix the strand member in the folded configuration. A variety of suitable connecting members may be used including pins, sutures, hoops or rings, clips and clamps. For example, Fig. 14 illustrates a pin 53 extending through the folds of the strand member, Fig. 15 illustrates a ring 54 positioned around the folded section of the strand member, and Fig. 16 illustrates a clip 55 positioned around the folded section of the strand member, to hold the strand member in the folded configuration. In an alternative embodiment, the length of the strand member is adjustable by heat shrinking or chemically shrinking the strand member, to decrease a length thereof. For example, the strand member can be formed of a heat shrinkable material, or the material may be chemically shrunk by solvent removal.

In another embodiment of the invention, illustrated in Fig. 17, an assembly is provided comprising the artificial chordae of the invention and at least one stopping member 56 configured to secure to the sutures. The stopping member is secured to the pair of sutures after the sutures are stitched through the heart tissue to prevent the sutures from slipping out of the tissue, but without the requirment of tying the two sutures into a knot. In the embodiment illustrated in Fig. 17 the stopping member comprises a clip 57 which secures to the sutures by gripping the sutures between inwardly tensioned arms of the clip. However, a variety of suitable stopping members may be used including clamps, rings, hoops, and the like. For example, Fig. 18 illustrates an alternative embodiment in which the stopping member comprises a tube 58 having a bore configured

to slidably receive one or more of the sutures of the pair of sutures, and having a fastening member, such as a fastener having a variable inner diameter with a reduced inner diameter configuration which frictionally engages the suture, to secure the suture to the tube.

In the embodiment illustrated in Fig. 18 the stopping member is secured to the second pair of sutures 17 along a length thereof so that a length of the sutures 17 extends between the heart valve leaflet edge and the papillary muscle. The stopping member is configured to quickly and easily secure to the sutures, so that the stopping member can be used to hold the suture in place without the length of the suture spanning the distance between the papillary muscle and valve leaflet changing. Thus, even if the length of the strand member is not correctly sized to correspond to the distance between the papillary muscle and the valve leaflet edge, the artificial chordae can be implanted using the stopping member so that a combined length of the strand member and the sutures is correctly sized to correspond to the distance between the muscle and valve leaflet. For example, the physician can attach the first end of the strand member to the papillary muscle, stitch the second pair of sutures through the valve leaflet so that the strand member or the strand member and a length of the second pair of sutures corresponds to the distance between the papillary muscle and the attachment location on the valve leaflet, and secure the stopping member to the second pair of sutures quickly and without longitudinally displacing the second pair of sutures further one way or another through the valve leaflet. It would be obvious to one of ordinary skill in the art that one or more stopping members may be used on one or both of the first 16 and second 17 pair of sutures.

Thus, the artificial chordae of the invention may be provided in two or three different sizes having strand members with different lengths, so that the physician can choose an artificial chordae that is

approximately the correct size and then adjust the size, as described above, to more exactly fit the patient.

In an alternative embodiment of the invention, illustrated in Fig. 19, the artificial chordae 60 comprises a suture 61 having a first end and a second end, and at least one stopping member 62 on either end thereof configured to secure to the suture. As discussed above, the stopping member can be secured to the suture to hold it in place without the disturbing or changing the length of the suture spanning the distance between the papillary muscle and valve leaflet. In the method of attaching the artificial chordae 60, the suture 61, which may be formed using conventional suture materials and dimensions, first end is stitched through the papillary muscle from a first side to a second side of the muscle, and the first stopping member is positioned on the first end of the suture adjacent to second side of the muscle, and the stopping member is secured to the suture. The second end of the suture is similarly stitched through the valve leaflet edge so that a length of the suture conforms to the length between the papillary muscle and valve leaflet edge. The second stopping member is then secured to the second end of the suture as above, without longitudinally displacing the suture and changing the length of the suture between the papillary muscle and the valve leaflet edge. In the embodiment illustrated in Fig. 19, the stopping member comprises a clip 57, as discussed above. Thus, the artificial chordae can be correctly sized and implanted quickly and easily.

While the present invention has been described in terms of certain preferred embodiments, those skilled in the art will recognize that modifications and improvements may be made to the invention without departing from the scope thereof. For example, the artificial chordae may be made of a plurality of braided strands, a biopolymer or a biopolymer-

synthetic composite, including degradable or nondegradable materials which may be physical blends or copolymers.

WHAT IS CLAIMED IS:

1. Artificial chordae for a heart valve, comprising:

a) at least one strand member having a first end and a second end, and being configured to extend from a papillary muscle to a location on the heart valve; and

b) a first pair of sutures extending from the first end of the strand member and a second pair of sutures extending from the second end of the strand member.

2. The artificial chordae of claim 1 wherein the location on the heart valve is a valve leaflet edge.

3. The artificial chordae of claim 1 wherein the strand member is from about 75 cm to about 90 cm in length.

4. The artificial chordae of claim 1 wherein the sutures are from about 1 cm to about 6 cm in length.

5. The artificial chordae of claim 1 wherein the strand member and the sutures are formed from one unitary piece of material.

6. The artificial chordae of claim 1 wherein the strand member and the sutures are formed from expanded polytetrafluoroethylene.

7. The artificial chordae of claim 6 wherein the expanded polytetrafluoroethylene is selected from the group consisting of polytetrafluoroethylene suture material and polytetrafluoroethylene fabric.

8. The artificial chordae of claim 1 having at least two

strand members, with the first ends of the strand members fixed together to form a joined end, wherein the strand members are longitudinally juxtaposed, and having one pair of sutures extending from the joined end, and a pair of sutures extending from the second end of each strand member.

9. The artificial chordae of claim 8 wherein the strand members are of equal lengths.

10. The artificial chordae of claim 1 wherein at least one pair of sutures includes a pledget at an interface between the sutures and the stand member.

11. The artificial chordae of claim 1 wherein at least one pair of sutures includes a stopping member configured to secure to the sutures.

12. The artificial chordae of claim 11 wherein the stopping member comprises a clip configured to grippingly secure to the pair of sutures.

13. The artificial chordae of claim 1 wherein the stopping member comprises a tube having a bore configured to slidably receive one or more of the sutures of the pair of sutures, and having a fastening member to secure the suture to the tube.

14. The artificial chordae of claim 1 wherein the strand member has a length that is adjustable.

15. The artificial chordae of claim 15 wherein the strand member is formed of a material that is heat shrinkable or chemically shrinkable.

16. The artificial chordae of claim 15 wherein the strand member is foldable and including a connecting member for connecting one or more folds of the strand member together.

17. The artificial chordae of claim 16 wherein the connecting member is selected from the group consisting of pins, sutures, and clamps, rings.

18. A heart valve chordae sizing gauge for measuring the distance between a papillary muscle and a location on a heart valve, comprising a shaft having a first end and a second end, and a transverse member spaced a distance between the first and second ends of the shaft.

19. The sizing gauge of claim 10 wherein the distance between the transverse member and the second end of the shaft is substantially equal to the distance between the papillary muscle and a valve leaflet edge of the heart valve.

20. The sizing gauge of claim 10 wherein the transverse member is mounted so as to slide along the shaft, and further including a means for releasably locking the transverse member onto the rod.

21. The sizing gauge of claim 10 having a handle on the first end of the shaft.

22. A method of attaching an artificial chordae in a heart, comprising:

a) providing an artificial chordae, comprising:

at least one strand member having a first end and a second end, and configured to extend from a papillary muscle to a location on the heart valve; and

a first pair of sutures extending from the first end of the strand member and a second pair of sutures extending from the second end of the strand member; and

b) attaching the sutures to the papillary muscle and to the heart valve, to attach the artificial chordae in the heart.

23. The method of claim 22 wherein the step of attaching the sutures further comprises:

a) stitching the first pair of sutures through a valve leaflet edge and tying the two sutures into a knot so that the first end of the strand member is secured to the valve leaflet edge; and

b) stitching the second pair of sutures through the papillary muscle and tying the two sutures into a knot so that the second end of the strand member is secured to the papillary muscle.

24. The method of claim 23 wherein the artificial chordae is attached by first attaching the first pair of sutures to a valve annulus of a heart valve prosthesis before the heart valve prosthesis is implanted, and then attaching the second pair of sutures to the papillary muscle after the heart valve prosthesis is implanted.

25. The method of claim 22 including, before step a, the step of measuring the distance between the papillary muscle and the location on the heart valve with a heart valve chordae sizing gauge, the gauge comprising a shaft having a first end and a second end, and a transverse member spaced a distance between the first and second ends of the shaft.

26. The method of claim 25 wherein the measuring step comprises holding the sizing gauge between the papillary muscle and a valve leaflet edge so that the second end of the sizing gauge contacts the papillary muscle and sliding the transverse member along the shaft until the member contacts the valve leaflet edge.

27. The method of claim 22 wherein at least one pair of sutures includes a stopping member configured to secure to the sutures, and wherein the step of attaching the sutures to the papillary muscle includes the step of stitching the pair of sutures through the papillary muscle from a first side to a second side of the papillary muscle, and securing the stopping member to the suture at a location on the suture adjacent the second side of the papillary muscle, to thereby prevent the displacement of the suture from the second side to the first side of the papillary muscle.

28. The method of claim 22 wherein at least one pair of sutures includes a stopping member configured to secure to the sutures, and wherein the step of attaching the sutures to the heart valve includes the step of stitching the pair of sutures through a valve leaflet edge from a first side to a second side of the valve leaflet edge, and securing the stopping member to the suture at a location on the suture adjacent the second side of the valve leaflet

edge, to thereby prevent the displacement of the suture from the second side to the first side of the valve leaflet edge.

29. The method of claim 22 wherein the strand member has a length that is adjustable, and including the step of adjusting the length of the strand member to conform to a length between the papillary muscle and a location of the heart valve.

30. The method of claim 29 wherein the step of adjusting the length of the strand member includes the step of folding a length of the strand member, and connecting the folds together to decrease the length of the strand member.

31. The method of claim 29 wherein the step of adjusting the length of the strand member includes heat shrinking or chemically shrinking the strand member to decrease the length of the strand member.

32. An artificial chordae for a heart valve of a patient's heart, comprising:

a) a suture having a first end and a second end; and

b) a first stopping member on the first end, and a second stopping member on the second end, each securing member being configured to secure to the suture, to thereby secure the suture within the patient's heart.

33. The artificial chordae of claim 32 wherein the stopping member comprises a clip configured to grippingly secure to the suture.

34. The artificial chordae of claim 32 wherein the stopping member comprises a tube having a bore configured to slidably

receive the suture, and having a fastening member to secure the suture to the tube.

35. A method of attaching an artificial chordae in a patient's heart, comprising:

a) providing an artificial chordae comprising

a suture having a first end and a second end; and

a first stopping member on the first end and a second stopping member on the second end, each stopping member being configured to secure to the suture for securing the suture within the patient's heart;

b) attaching the first end of the suture to a papillary muscle of the patient's heart by stitching the first end of the suture through the papillary muscle from a first side of the muscle to a second side of the muscle, and positioning the stopping member at a location on the suture adjacent the second side of the papillary muscle, and securing the stopping member to the suture to thereby prevent the displacement of the suture from the second side to the first side of the papillary muscle; and

d) attaching the second end of the suture to a valve leaflet edge of the patient's heart by stitching the second end of the suture through the valve leaflet edge at a location on the valve leaflet edge from a first side of the valve leaflet edge to a second side of the valve leaflet edge so that a length of suture conforms to a length between the papillary muscle and the location on the valve leaflet edge, and positioning the stopping member at a location on the suture adjacent the second side of the valve leaflet edge, and securing the stopping member to the suture to thereby prevent the displacement of the suture from the second side to the first side of the valve leaflet edge.

FIG. 1
PRIOR ART

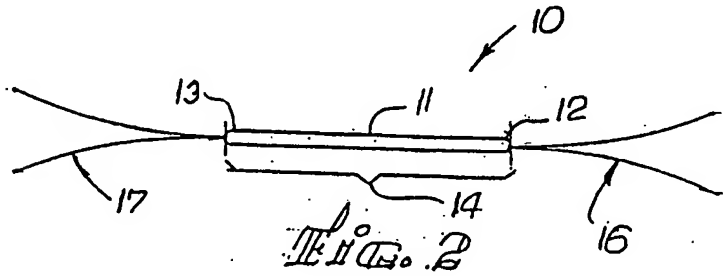

FIG. 2

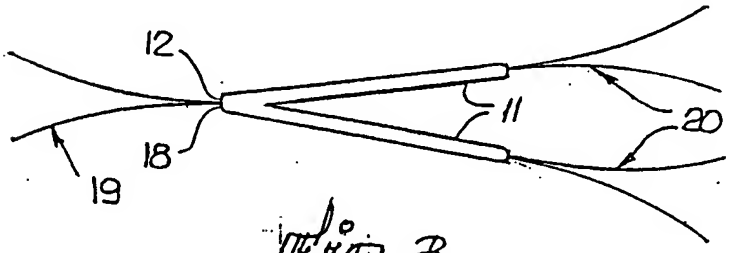

FIG. 3

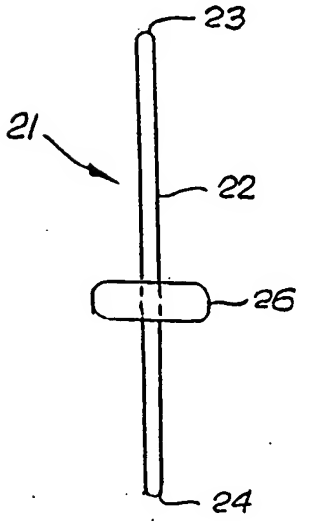

FIG. 4

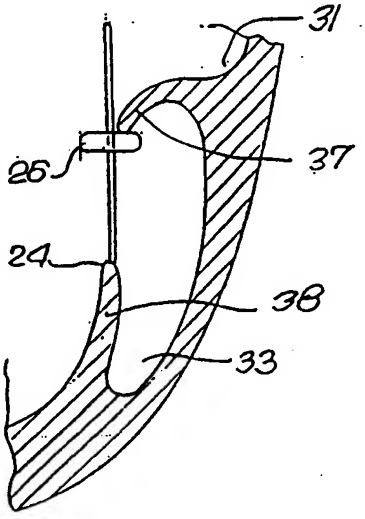

FIG. 5

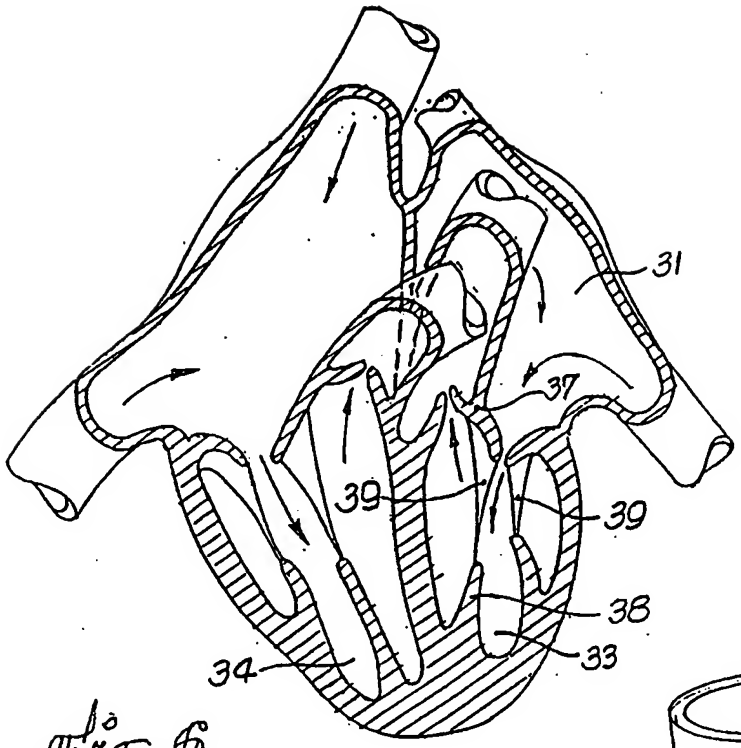

FIG. 6

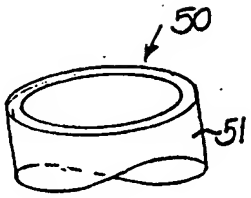

FIG. 10

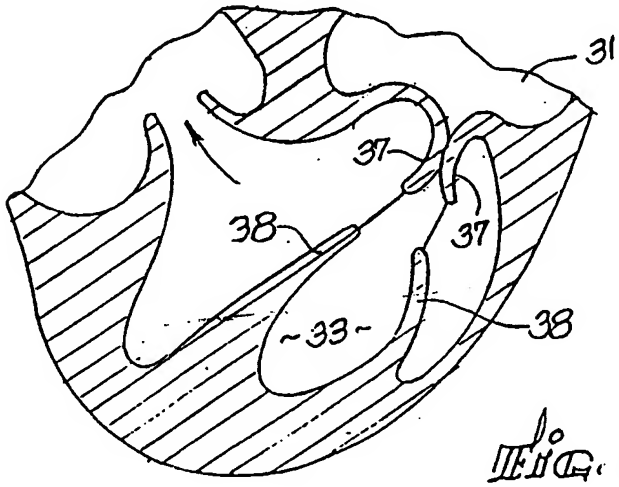

FIG. 7

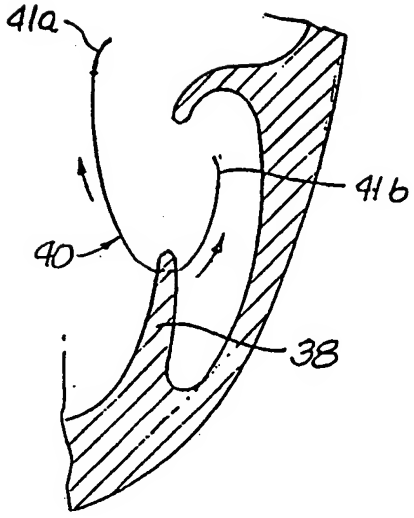

FIG. 8A
PRIOR ART

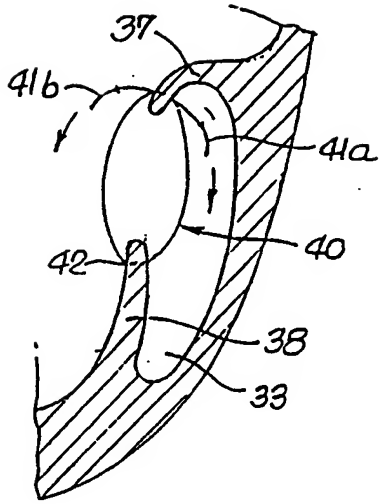

FIG. 8B
PRIOR ART

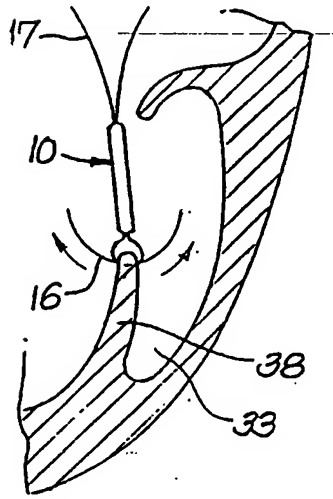

FIG. 9A

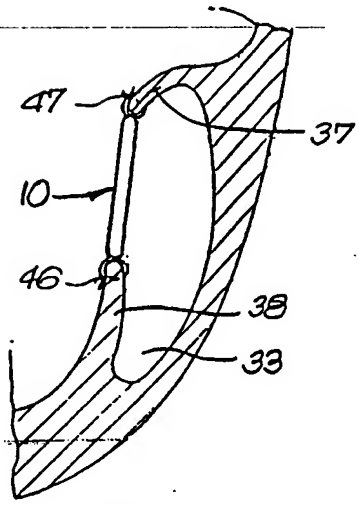

FIG. 9B

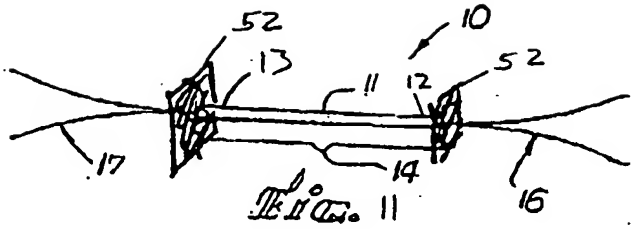

Fig. 11

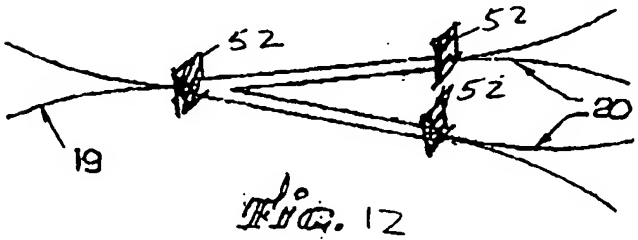

Fig. 12

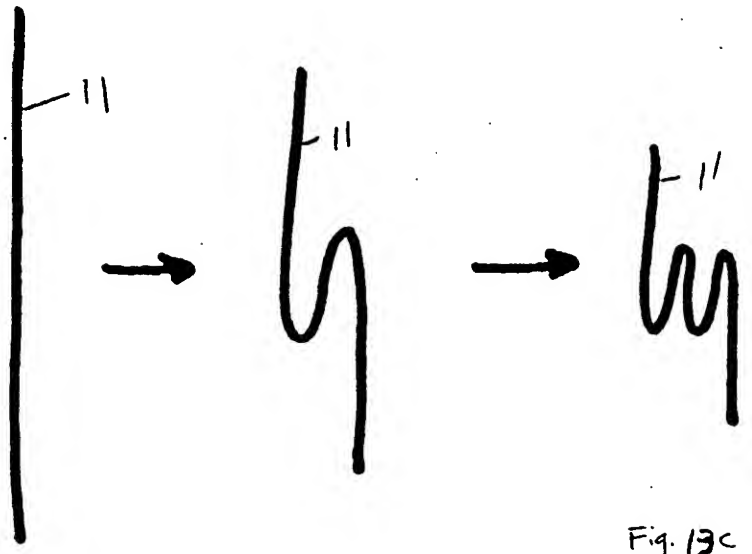

Fig. 13a Fig. 13b Fig. 13c

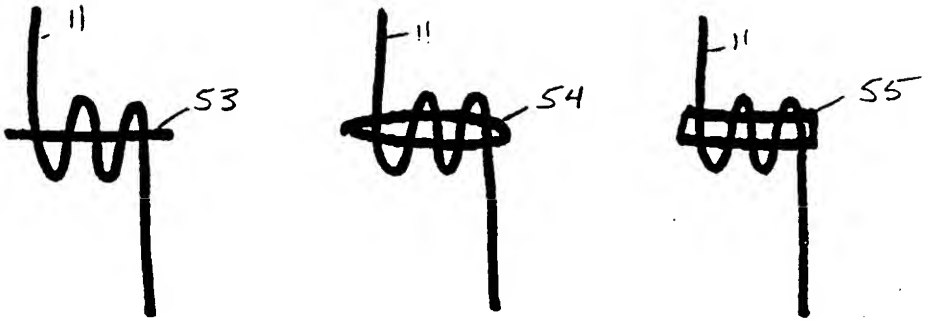

Fig. 13d Fig. 13e Fig. 13f

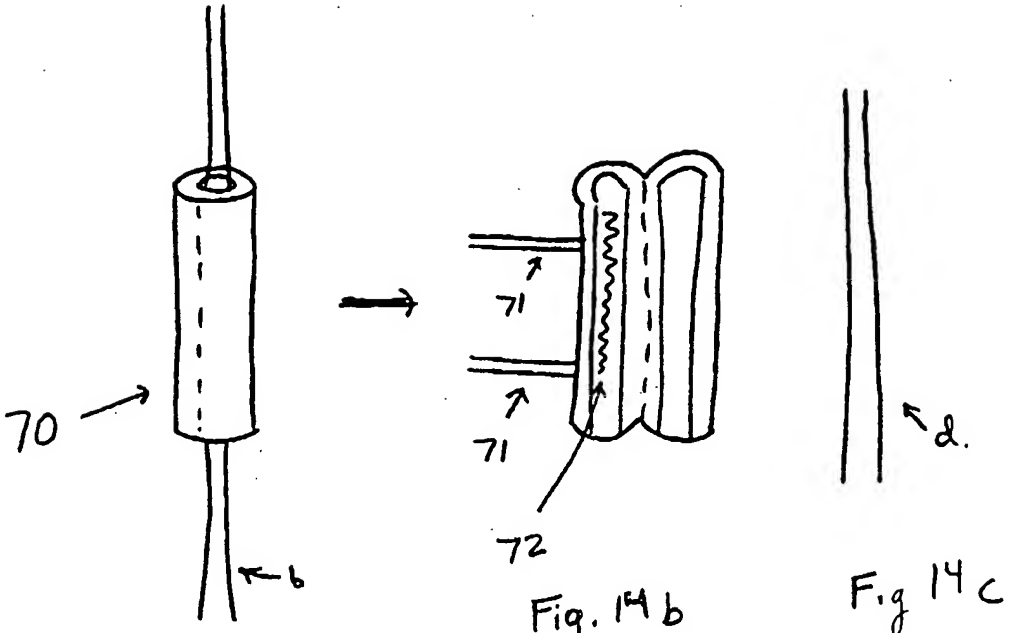

Fig 14a

Fig. 14b

Fig 14c

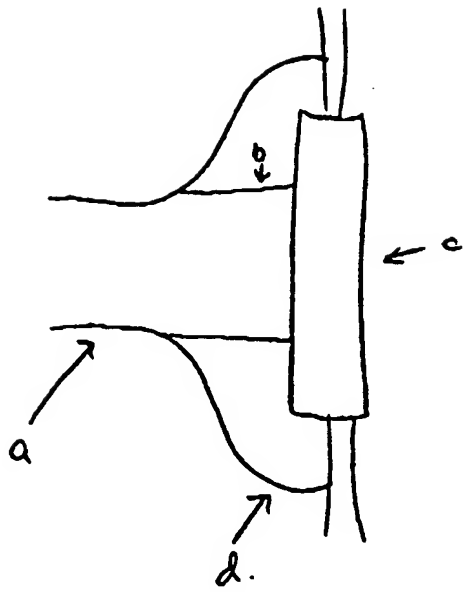

Fig 15

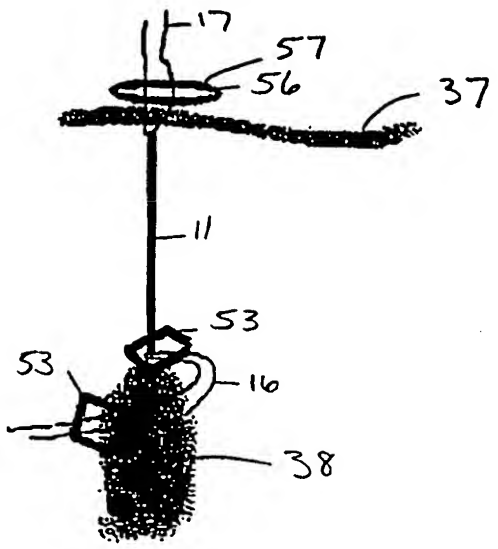

Fig. 17

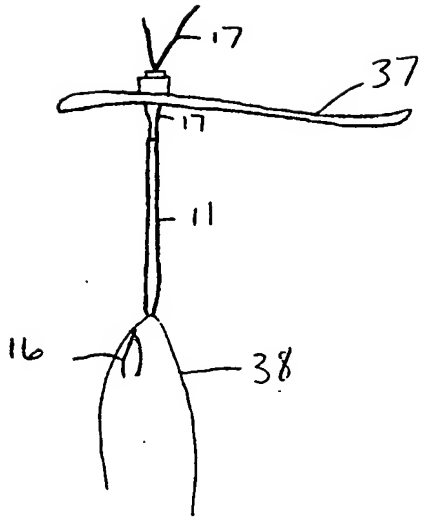

Fig. 18

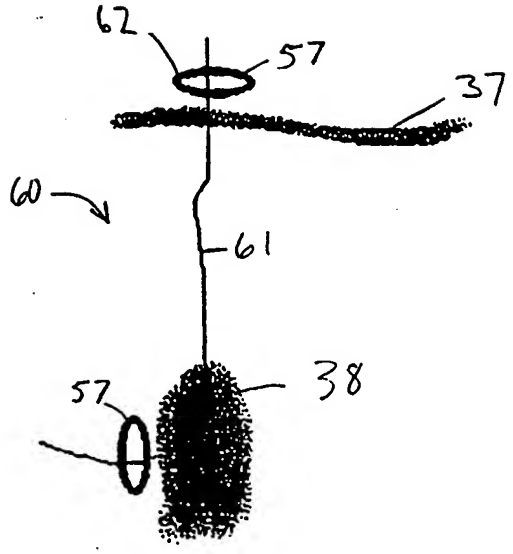

Fig. 19

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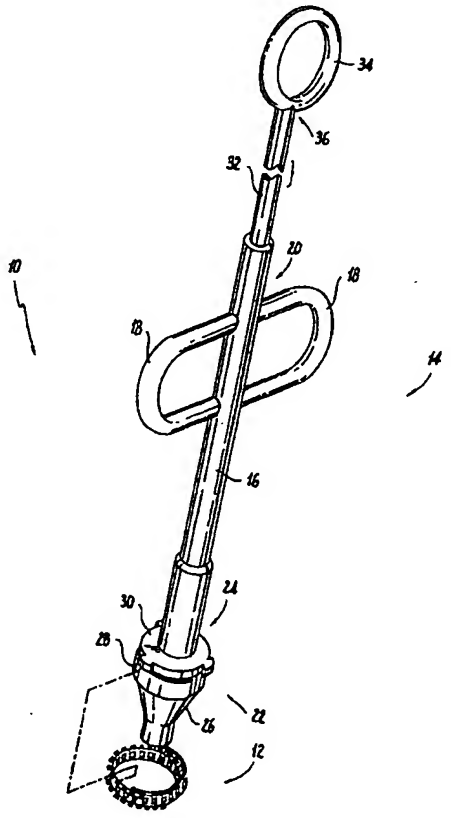
(54) Title: HEART VALVE REPLACEMENT TOOLS AND PROCEDURES

(57) Abstract

Disclosed are various systems for installing a heart valve within a patient. In a first system, there is provided a heart valve installation assembly (64) and an expandable heart valve ring installation assembly (10), each of which comprises a separate tool. The expandable heart valve ring assembly is provided to position and expand a heart valve ring (12) into engagement with tissue. The valve installation assembly is provided to position and engage the heart valve (70) with the expandable heart valve ring. In a second system, the heart valve installation assemblies and expandable ring installation assemblies are provided on a single tool or instrument (140). Also disclosed are various methods of installing an expandable heart valve ring within a heart and positioning and installing an artificial synthetic heart valve within the expanded heart valve ring.



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HEART VALVE REPLACEMENT TOOLS AND PROCEDURES

BACKGROUND

1. Technical Field

The subject disclosure relates to minimally invasive surgical procedures and apparatus and, more particularly, to instruments and methods for performing heart valve replacement surgery.

2. Background of Related Art

The diagnosis and treatment of coronary disease and related conditions often requires repair or replacement of the valves located within the heart. Various factors, such as, for example, calcification, may result in the mitrial or aortic valves becoming impaired or functionally inoperative requiring replacement. Where replacement of a heart valve is indicated, in general, the dysfunctional valve is cut out and replaced with either an artificial, synthetic heart valve or a harvested porcine heart valve. The replacement valve is typically sutured in place of the original valve.

It is common to access the heart in a patient's thoracic cavity by making a longitudinal incision in the chest. This procedure, referred to as a median sternotomy includes cutting through the sternum and forcing the two opposing halves of the rib cage to be spread apart allowing access to the thoracic cavity and thus the heart.

Instruments particularly suitable for spreading and holding apart the halves of the rib cage are marketed by States Surgical Corporation, Norwalk, Connecticut. The MINI-CABG® UNIVERSAL BASE RETRACTOR includes a substantially planar base having an opening which can be positioned on the patient such that the opening overlies the incision at the operative site. Retractor blades, such as the MINI-CABG® retractors, are slidably mounted on the base and are provided to spread apart the rib cage halves and engage and retract obstructing tissue. The base may also be provided with surgical instruments which can be used to stabilize or

manipulate the heart during surgery such as the MINI-CABG® HEART STABILIZER AND SITE MANIPULATOR.

Once access to the thoracic cavity has been achieved, surgery on the heart to effect valve replacement may be performed. During some procedures, the heart beat is arrested by infusion of a cardioplegic fluid, such as potassium chloride (kcl), to paralyze the myocardium while blood flow circulation is maintained through known heart bypass techniques. Alternatively, the heart is allowed to beat to maintain circulation, while a localized area of the heart, on which surgery is to be performed, is locally immobilized.

The heart is incised and the defective valve is cut away leaving a surrounding area of locally tougher tissue. Known heart valve replacement techniques typically include individually passing sutures through the tough tissue to form an array of sutures. Free ends of the sutures are extended out of the thoracic cavity and laid, spaced apart, on the patient's body. The free ends of the sutures are then individually threaded through an edge around the circumference of the replacement valve or a supporting cuff. Once all sutures have been run through the valve, all the sutures are pulled up taught and the valve is slid or "parachuted" down into place adjacent the tough tissue. Thereafter, the replacement valve is secured in place using the sutures.

Where replacement is performed utilizing an artificial valve, hand held instruments in the form of a stick, may be affixed to the valve and used to manipulate the replacement valve into place. The commercially available replacement valves are typically provided with a detachable holder structure which can be engaged by the hand tools.

While the above described procedures are sufficient to successfully position a heart valve within the heart, they are particularly time consuming.

Therefore, a need exists for apparatus and procedures of quickly and efficiently positioning and affixing artificial heart valves within the heart.

SUMMARY

There are provided various embodiments of systems and methods for installing a synthetic, artificial heart valve within a patient. The first system generally includes two assemblies such as, an expandable ring installation assembly and a heart valve installation assembly. A separate tool is associated with each assembly. The ring installation assembly includes a ring installation tool which is provided to releasably engage an expandable heart valve ring. The ring, when positioned at the site of the removed natural heart valve, can be expanded into place so as to engage tissue and form an anchor for later insertion of the heart valve. The ring installation tool includes structure for releasably holding the expandable heart valve ring and camming structure for expanding the expandable heart valve ring from a first diameter to an increased second diameter and into engagement with tissue.

The novel heart valve ring utilized with the first assembly generally includes an elongated strip of metallic or biocompatible material having a plurality of latches which are configured to engage corresponding openings in the material when manipulated to form a ring. The latches and openings operate in ratchet form to maintain heart valve ring in an expanded condition. Additionally, the heart valve ring may preferably be provided with tabs extending generally perpendicularly to the surface of the ring. The tabs are provided to engage tissue so as to assist in anchoring the heart valve ring to tissue and to secure the heart valve to the heart valve ring. Additionally, the heart valve ring may include inwardly projecting teeth which are configured to engage a heart valve or a cuff surrounding a heart valve to assist in holding the heart valve to the expandable ring.

The second assembly or heart valve installation assembly includes a second tool or valve installation tool which is configured to releasably hold a synthetic heart valve, which typically includes its own heart valve holder structure, and position the heart valve within the expanded heart valve ring. The valve installation tool includes a valve positioner which is movable relative to a housing of the tool so as to drive the heart valve into engagement with the expandable ring. Preferably, the heart valve installation tool includes a release mechanism for releasing the heart valve once it has been positioned within the heart valve ring and grasping structure so as to engage the housing of the heart valve installation tool in stationary relationship relative to the heart valve ring.

A method of installing a heart valve within a patient utilizing the first system is provided and generally includes positioning an expandable heart valve ring on a ring installation tool and positioning the heart valve ring at the operative site within the patient's heart. Preferably, the expandable heart valve ring is provided with a synthetic graft material surrounding it so as to facilitate continuing growth and securement to the heart valve tissue. The heart valve ring is subsequently expanded into engagement with the heart tissue and is released from the heart valve installation tool. The heart valve ring installation tool is preferably removed from the operative site. A valve installation tool containing an artificial heart valve, preferably having valve holder structure such as two members (halves) for engaging the valve, is positioned adjacent the expanded heart valve ring. Preferably, grasping structure on the valve installation tool is engaged with the expanded heart valve ring and the valve positioner is actuated so as to drive the heart valve into engagement with the heart valve ring. Once the heart valve has been affixed within the heart valve ring a release mechanism may be actuated to release the heart valve from the valve installation tool and the valve installation tool removed from the operative site. Subsequently, a suture

holding the valve holder halves may be cut to release the valve holder halves supplied with the artificial heart valve and removed from the operative site.

In a second system, the expandable ring installation assembly and the heart valve installation assembly are provided together in a single or "one shot" tool. The valve installation assembly generally includes a housing having structure for frictionally retaining a synthetic heart valve thereon. Notably, the heart valve holder generally supplied with the heart valve is not utilized in the second system. A ring installation assembly is movable relative to, and extends generally through, the valve installation assembly. The ring installation assembly includes structure at a distalmost end for releasably retaining the expandable heart valve ring. Camming structure is provided on the ring installation assembly for expanding the expandable heart valve ring into engagement with the heart tissue.

A method of utilizing a second system generally includes accessing the heart and positioning the system such that the expandable heart valve ring is adjacent the operative site. The tool may then be actuated to expand the expandable heart valve ring into engagement with the tissue. This occurs by moving camming structure associated with the ring installation assembly relative to the expandable heart valve ring. Once the heart valve ring has been expanded, the tool may be actuated to reverse the camming structure such that the holding structure may be passed downwardly through the heart valve ring. Thereafter, the valve installation assembly is actuated to drive the artificial heart valve down into engagement with the expandable heart valve ring. As noted above, preferably the expandable heart valve ring includes teeth to engage a cuff provided with the expandable heart valve. Once the heart valve has been installed within the heart valve ring, the second system may be removed by drawing the expanding and camming structure through the heart valve and out of the operative site.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments are described herein with reference to the drawings, wherein:

FIG. 1 is a perspective view of an expandable heart valve ring installation assembly which forms part of a two-part heart valve installation system;

FIG. 2 is a plan view of a first side of an expandable heart valve ring in a flat configuration prior to being manipulated to form a ring;

FIG. 3 is a plan view of a second side of the expandable heart valve ring of Fig. 2;

FIG. 4 is a sectional view of the expandable heart valve ring taken along line 4-4 of Fig. 3;

Fig. 5 is a partial sectional view of the expandable heart valve ring taken along line 5-5 of Fig. 3;

FIG. 6 is an end view of the expandable heart valve ring manipulated to form a ring;

FIG. 7 is a perspective view of a ring expander tool of the assembly of FIG. 1;

FIG. 8 is a partial sectional view of the ring expander tool of Fig. 7 in an actuated condition;

FIG. 9 is a sectional view taken along line 9-9 of Fig. 7;

FIG. 10 is a sectional view taken along line 10-10 of FIG. 8;

FIG. 11 is a perspective view of a heart valve installation assembly which forms a second part of the two-part heart valve installation system;

FIG. 12 is a view, with parts separated, of a heart valve installation tool of the assembly of FIG. 11;

FIG. 13 is a partial sectional view of the heart valve installation tool in an actuated state;

FIG. 14 is a perspective view of a patient with access to the thoracic cavity held open by a retractor;

FIG. 15 is a perspective view of a heart with natural valve removed and the assembled ring expander tool and expandable heart valve ring in position to be actuated;

FIG. 16 is an enlarged view of the distal end of the ring expander tool positioned at the operative site;

FIG. 17 is a view similar to Fig. 16 and illustrating expansion of the expandable ring into engagement with the surrounding tissue;

FIG. 18 is a view similar to Fig. 17 and illustrating release of the ring expander tool from the expanded heart valve ring;

FIG. 19 is a view illustrating removal of the ring expander tool from the operative site with the expanded heart valve ring fixed in place within the heart tissue;

FIG. 20 is a perspective view of the heart valve installation assembly being moved into the operative site;

FIG. 21 is a view illustrating the engagement of the heart valve installation tool with the implanted and expanded heart valve ring and advancement of a heart valve assembly toward the expanded heart valve ring;

FIG. 22 is a view similar to FIG. 21 illustrating actuation of the heart valve installation tool to position the heart valve assembly within the expanded heart valve ring;

FIG. 23 is a view of the heart valve installation tool detached from the heart valve assembly and expanded heart valve ring;

FIG. 24 is a view of a heart valve holder being removed from a heart valve;

FIG. 25 is a view of the expanded heart valve ring and heart valve secured thereto within the heart tissue;

FIG. 26 is a perspective view of an alternate embodiment of a heart valve installation system including a single shot instrument for installing an expandable heart valve ring and replacement heart valve;

FIG. 27 is a perspective view of the single shot instrument of Fig. 26, with parts separated;

FIG. 28 is a sectional view of the single shot instrument;

FIG. 29 is a view, partially shown in section of the single shot instrument during actuation;

FIG. 30 is a perspective view of a heart with the natural valve removed and the single shot instrument with an expandable heart valve ring and heart valve assembled thereon and in position to be actuated;

FIG. 31 is a plan view of the assembly of Fig. 30 with the distal end of the single shot instrument and expandable heart valve ring positioned at the installation location within the heart;

FIG. 32 is a view of the distal end of the ring installation assembly of the single shot instrument expanding the heart valve ring into engagement with the heart;

FIG. 33 is a view similar to Fig. 32 with the heart valve ring expanded and affixed to heart tissue and the distal end of the ring installation assembly in a collapsed condition;

FIG. 34 is a perspective view of the single shot instrument actuating the valve installation assembly to advance the heart valve toward the expanded heart valve ring;

FIG. 35 is a perspective view of the heart valve positioned within the expanded heart valve ring;

FIG. 36 is a view of the distal end of the single shot instrument being withdrawn through the heart valve; and

FIG. 37 is a perspective view of the heart valve being affixed to the expanded heart valve ring.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Various embodiments are disclosed herein which relate to installation systems including tools and methods for positioning and securing a synthetic replacement heart valve within the heart without the necessity of manually suturing the valve in place. The disclosed systems accomplish this by implanting a base or anchor in the form of an expandable ring into the heart tissue and to which the synthetic heart valve may be affixed. In a first embodiment, a two tool installation system is provided which generally includes a ring installation assembly and a separate heart valve installation assembly.

Referring now to Fig. 1, there is disclosed a ring installation assembly 10 which includes a novel heart valve ring 12 and a ring expander tool 14 which is provided to implant heart valve ring 12 within the heart tissue. Ring expander tool 14 includes a housing 16 having a pair of handles 18 at a proximal end 20 thereof. An expander assembly 22 is provided on distal end 24 of housing 16. Expander assembly 22 is provided to releasably engage heart valve ring 12 and expand heart valve ring 12 in a manner described hereinbelow. As used herein, the term "distal" refers to that

portion of the assembly, or component thereof, further from the user while the term "proximal" refers to that part of the assembly, or component thereof, closer to the user.

Expander assembly 22 generally includes a nose cone 26 and an expansion sleeve 28 surrounding nose cone 26. Expansion sleeve 28 is preferably formed of a shape memory or spring steel material and is configured to assume a reduced diameter at rest. A back plate 30 is provided adjacent distal end 24 of housing 16 to maintain heart valve ring 12 in position about expansion sleeve 28. Ring expander tool 14 additionally includes a plunger 32 which is slidably mounted within housing 16 and is provided to actuate expander assembly 22. Plunger 32 has a handle 34 at a proximal end 36 thereof. Movement of plunger 32, distally and proximally, relative to housing 16 causes expansion sleeve 28 to be expanded and reduced, respectively, in diameter in a manner described hereinbelow so as to expand and release heart valve ring 12.

As noted hereinabove, ring installation assembly 10 includes a novel heart valve ring 12 which is radially expandable to engage heart tissue and thereby provide a base or anchor for securing a synthetic heart valve thereto. Expandable heart valve ring 12 is generally formed as a strip of suitable biocompatible material such as, for example, stainless steel. Heart valve ring 12 is manipulatable from a strip to a ring. Referring now to Fig. 2, a plurality of openings 38 are provided along the length of heart valve ring 12. Latches 40, located generally centrally within heart valve ring 12, are provided to engage openings 38 in ratchet fashion so as to secure heart valve ring 12 in an expanded position. In order to facilitate securing heart valve ring 12 to the walls of heart tissue, opposed tabs 44 are provided along the edges of heart valve ring 12 and are configured to penetrate and engage heart tissue. There are also provided a plurality of teeth 42 which engage a heart valve or cuff thereon once

the heart valve has been positioned within heart valve ring 12. Openings 38 and latches 40 as well as teeth 42 and tabs 44 may be formed in a strip of suitable heart valve ring material by die punching. Other methods of forming the heart valve ring, such as, molding, machining, etc. are also contemplated.

As shown in Figs. 2-4, a first end 46 of heart valve ring 12 is generally devoid of tabs 44 while a second end 48 of heart valve ring 12 includes tabs 44. This is to provide a degree of overlap as first end 46 is positioned within second end 48 when manipulated to form a ring so as to avoid duplicate tabs 44 projecting and overlapping each other. As shown in Figs. 4 and 5, when folded over, tabs 44 project from heart valve ring 12 in a first direction to engage tissue while teeth 42 project from heart valve ring 12 in an opposite direction to engage a heart valve. Latches 40 generally project from heart valve ring 12 in the same direction as tabs 44.

Referring now to Fig. 6, there is illustrated heart valve ring 12 manipulated to form a generally circular ring with first end 46 generally on the interior of the ring and second end 48 generally facing exteriorly of the ring.

Referring now to Figs. 7 and 8, in order to actuate ring expander tool 14 and expand heart valve ring 12 from a generally reduced state to an expanded state, expander assembly 22 generally includes a tapered wedge 50 which is provided at a distal end 52 of plunger 32. A stop 54 extends distally from tapered wedge 50. Tapered wedge 50 is movable within a tapered bore 56 formed in nose cone 26 in response to movement of plunger 32. An abutment surface 58 is provided at a distal end of nose cone 24 to engage stop 54 on plunger 32 (FIG. 8).

Referring now to Figs. 7-10, a plurality of radially projecting walls 60 are provided within slots 62 formed in nose cone 26. Walls 60 are configured to engage tapered wedge 50 as tapered wedge 50 is moved distally. Thus, as shown in Figs. 7 and 9, when plunger 32 is in a proximal position, tapered wedge 50 does not

engage walls 60 and expansion sleeve 28 remains in a reduced first diameter "d1". However, as shown in Figs. 8 and 10, as plunger 32 is driven distally with respect to housing 16, tapered wedge 50 drives walls 60 outwardly to thereby force expansion sleeve 28 radially outwardly to an expanded second diameter "d2" greater than that of the first diameter.

Referring now to Fig. 11, there is disclosed a heart valve installation assembly 64 associated with the two-part heart valve installation system. Heart valve installation assembly 64 generally includes a heart valve assembly 66. Heart valve installation assembly 66, generally includes a holder 68 which is preferably formed in holder halves 68a and 68b and a heart valve 70. Heart valve 70 generally includes an outer ring or cuff 72 having a plurality of leaflets 74 pivotally mounted therein. Flanges 76 on holder halves 68a and 68b are configured to engage interior edges of ring 72 to hold heart valve 70 in position for surgery. Holder halves 68a and 68b define a bore 78 therebetween which is configured to engage structure on a valve installation tool.

Heart valve installation assembly 64 additionally includes a valve installation tool 80. Valve installation tool 80 is provided to position heart valve 70 within expandable ring 12. Installation tool 80 includes a housing 82 having a shaft 84 extending proximally therefrom. Shaft 84 is formed with a threaded surface 86. Valve installation tool 80 additionally includes a valve positioner 88 slidably mounted relative to housing 82. Specifically, a drive shaft 90 of valve position 88 is slidably mounted within housing 82 and includes a valve driver 92 positioned at a distal end 94 of drive shaft 90. A drive knob 96 is positioned at a proximal end 98 of drive shaft 90. Drive knob 96 is affixed to drive shaft 90 such that drive knob 96 is free to rotate relative to drive shaft 90. Valve positioner 88 is also provided with a release mechanism including a release knob 100. Drive knob 96 and release knob 100 are

provided with knurled surfaces 102, 104, respectively, to facilitate operation by the user.

At least one, and preferably three, guide bars 106 are affixed at their proximal ends 108 to wings 110 formed on housing 82. Guide bars 106 extend distally from wings 110 and terminate in hooks 112 formed at distal ends 114 of guide bars 106. Hooks 112 are provided to engage heart valve ring 12 once heart valve ring 12 has been imbedded into tissue. By engaging heart valve ring 12 with hooks 112, housing 82 is positioned stationary relative to heart valve ring 12 and permits movement of valve positioner 88 and heart valve assembly 66 without displacing heart valve ring 12. Wings 116 are provided on valve driver 92 and are slidably mounted over guide bars 106 to facilitate alignment and positioning of valve assembly 66, carried by valve driver 92, relative to heart ring 12.

As shown in Fig. 12, valve positioner 88 additionally includes a release shaft 118 which is slidably mounted within drive shaft 90. A threaded proximal end 120 of release shaft 118 engages release knob 100 to affix release shaft 118 to release knob 100. A threaded surface 122 is provided at a distal end 124 of release shaft 118 and is configured to engage a portion of valve holder 68. Release shaft 118 is slidably mounted within a bore 126 of drive shaft 90.

Referring now to Fig. 13, drive knob 96 is provided with a threaded inner surface 128 which, when positioned adjacent shaft 84 of housing 82, engages threaded surface 86. Thus, by rotating drive knob 96 relative to housing 82, drive shaft 90 and thus valve driver 92 can be moved in precise and definite amounts relative to hooks 112 and thus expanded heart valve ring 12.

With reference to Figs. 14-25, the method of using the two tool installation system to install an artificial heart valve within a patient will now be described. Referring initially to Fig. 14, access to the heart through the thoracic

cavity is accomplished using well known surgical procedures. Generally, an incision I is made through the sternum of a patient P to access the thoracic cavity TC and expose the heart H.

Preferably, access to the cavity is maintained with the assistance of a retractor R. Retractor R generally includes an oval planar base B. Retractor R is positioned on patient P such that an opening O defined by base B overlies incision I. A plurality of retractor blades R1, R2, R3 ... are slidably mounted on base B and engage and retract the tissue edges of incision I. Optionally, additional instruments may be affixed to base B to manipulate and/or stabilize the heart H to facilitate surgery thereon. Blood flow circulation is maintained using known techniques. Thus, access to heart H is achieved and maintained. Other known open surgical procedures to access the heart are also contemplated and may be substituted for the procedure described herein.

Once access to heart H has been obtained, heart H is opened and the dysfunctional valve is removed using known surgical procedures. Referring now to Fig. 15, ring installation assembly 10 is prepared by positioning heart valve ring 12 about expander assembly 22. Preferably, a natural or synthetic graft material 130 is placed around heart valve ring 12. Graft material 130 protects both heart H and heart valve ring 12 and facilitates tissue ingrowth to assist in holding heart valve ring 12 in place within the heart after expansion.

Ring installation assembly 10 is then manipulated to position expander assembly 22, and thus heart valve ring 12, within the space V between the chambers of heart H previously occupied by the dysfunctional valve. When heart valve ring 12 is in the appropriate position within space V, ring expander tool 14 is actuated by moving plunger 32 distally relative to housing 16 to expand heart valve ring 12.

Specifically, as shown in Figs. 16 and 17, as plunger 32 is driven distally within housing 16, tapered wedge 50 engages and drives walls 60 radially outward forcing expansion sleeve 28 and thus heart valve ring 12 to move from an unexpanded state (FIG. 16) to an expanded state (FIG. 17). As heart valve ring 12 expands, it engages the heart tissue and wedges itself against the tissue. As noted hereinabove, latches 40 engage openings 38 (Fig. 3) to maintain heart valve ring 12 in the expanded state. Additionally, tabs 44 may become imbedded in the heart tissue to assist in securing heart valve ring 12 within space V in heart H. Distal advancement of tapered wedge 50 can be stopped when heart valve ring 12 is sufficiently wedged against heart H. Maximum expansion is obtained when stop 54 engages abutment surface 58 (Fig. 17).

It should be noted that variously dimensioned ring expander tools 14 may be provided to attain differing maximum expanded diameters depending on the ring size and type of replacement valve. Further, the final expanded diameter of heart valve ring 12 should be substantially the same diameter as the natural valve replaced and space V as well as being approximately the same diameter as, or slightly larger than, the diameter of the replacement valve. Plunger 32 can then be withdrawn proximally relative to housing 16 withdrawing tapered wedge 50 within bore 56.

Referring now to Figs. 18 and 19, as noted above, expansion sleeve 28 is formed of a spring or shape memory material such that when tapered wedge 50 is moved proximally within tapered bore 56, expansion sleeve 28 shrinks to a reduced diameter. As shown in Fig. 19, heart valve ring 12, with graft material 130 thereon, remains imbedded in heart H while ring expander tool 14 may be withdrawn from the heart H.

Referring now to Fig. 20, once heart valve ring 12 has been positioned within the heart, the second tool of the two-part installation system, specifically valve

installation tool 80, may be used to position valve assembly 66 within expanded heart valve ring 12. Preferably, heart valve ring 12 is provided with one or more suture loops 132 which are affixed to either heart valve ring 12 or to graft material 130. Suture loops 132 are configured to receive hooks 112 of valve installation tool 80 so that valve installation tool 80 may be secured in a stationary position with respect to heart valve ring 12. Initially, valve installation tool 80 is advanced towards heart valve ring 12 until hooks 112 provided on guide bars 106 securely engage suture loops 132. As shown in Fig. 21, once hooks 112 have been secured to suture loops 132, valve positioner 88 may be moved distally relative to housing 82 to drive valve assembly 66 towards heart valve ring 12. To do so, drive knob 96 is advanced distally relative to housing 82 such that drive shaft 90 and thus valve driver 92 are advanced toward heart valve ring 12. As noted hereinabove, guide bars 106 guide valve driver 92 along the lengths thereof. Valve positioner 88 is advanced distally with respect to housing 82 until drive knob 96 comes into contact with threaded surface 86 on shaft 84 of housing 82.

Referring now to Fig. 22, once drive knob 96 has reached threaded surface 86, drive knob 96 may be rotated such that a threaded interior surface 134 of a bore 136 in drive knob 96 threadingly engages threaded surface 86 of shaft 84 and moves drive shaft 90 distally. As noted above, drive knob 96 is configured to rotate independently of drive shaft 90. By engaging threaded interior surface 134 of drive knob 96 with threaded surface 86 of shaft 84, valve driver 92 and thus valve assembly 66 may be advanced in discreet and precise amounts relative to heart valve ring 12. Additionally, the engagement of drive knob 96 with shaft 84 allows an increased amount of force to drive ring 72 of heart valve 70 into position within heart valve ring 12. By securing hooks 112 to suture loops 132 and heart valve ring 12, heart valve ring 12 is retained in its stationary position. This push-pull action allows heart valve

ring 12 to remain imbedded in the heart without danger of pushing heart valve ring 12 out of position as heart valve assembly 66 is driven therein. Once heart valve 70 has been securely positioned within heart valve ring 12, release knob 100 may be rotated to unthread threaded surface 122 of release shaft 118 from valve holder halves 68a and 68b thereby disconnecting valve assembly 66 from valve positioner 88 as shown in Fig. 23. Valve installation tool 80 is disengaged from heart valve ring 12 by breaking or cutting suture loops 132 thereby releasing hooks 112 from heart valve ring 12. Thereafter, valve installation tool 80 may be removed from the operative site.

Referring now to Fig. 24, holder halves 68a and 68b may now be split apart such that flanges 76 are disengaged from ring 72 of heart valve 70. Preferably, a suture 69 is cut to release halves 68a and 68b from each other. Fig. 25 illustrates heart valve 70 positioned within heart valve ring 12 and is secured thereto by teeth 42. In order to further secure heart valve 70 to heart valve ring 12, several tabs 44 of heart valve ring 12 may be folded over ring 72 of valve 70 to thereby securely lock valve 70 to heart valve ring 12. Thus, the installation of the heart valve 70 within heart H is accomplished.

Referring now to Fig. 26, there is disclosed a second embodiment of a heart valve installation system having a single tool system or single shot tool 140 which is provided to install expandable ring 12, having graft material 130 therearound, into the heart and position and secure heart valve 70 within the expanded heart valve ring 12. Single shot tool 140 generally includes a valve installation assembly 142 and a ring installation assembly 144 which extends through valve installation assembly 142. Valve installation assembly 142 includes a housing 146 preferably formed as housing halves 146a, 146b. A flange 148 is provided at a distal end 150 of housing 146 and serves to hold valve 70. Finger rings 152 are provided

on a proximal end 154 of housing 146. Preferably, valve 70 is retained against flange 148 by a friction surface 156. As shown in this embodiment, no additional valve holder structure is necessary.

Ring installation assembly 144 generally includes a barrel 158, preferably formed as barrel halves 158a and 158b. A pair of relatively thin flexible expander legs 160 extend distally from barrel 158. Legs 160 are approximately one-sixteenth of an inch thick. Expander legs 160 are provided with recesses 162 at a distal end 164 of each of expander legs 160. Recesses 162 are configured to securely retain expandable heart valve ring 12 when heart valve ring 12 is in a reduced diameter configuration. A flange 166 is provided at the top of barrel 158. Ring installation assembly 144 additionally includes a ring expander knob 168 having a shaft 170 extending distally therefrom. Shaft 170 extends through barrel 158. Shaft 170 cooperates with an expander blade 172 positioned on a distal end of shaft 170. Preferably, ring expander knob 168 has a knurled surface 174 to facilitate actuation thereof. A threaded collar 176 having a threaded surface 178 is affixed within barrel halves 158a and 158b and slidably and rotatably supports shaft 170.

Referring now specifically to Figs. 27 and 28, single shot tool 140 is illustrated without an artificial valve or heart valve ring installed thereon. Threaded surface 178 of collar 176 is configured to engage a threaded surface 180 which extends partially along a bore 182 formed by barrel halves 158a and 158b. Shaft 170 additionally includes a tubular portion 184 movably mounted in collar 176 and a generally rectangular portion 186 extending distally therefrom. Expander blade 172 is provided at a distal end of rectangular portion 186. Rectangular portion 186 and expander blade 172 are dimensioned and configured to fit between leaflets of a valve. In order to expand a ring held within recesses 162, expander blade 172 is provided with a pair of camming surfaces 188 which cooperate with camming edges 190

formed on distal end 164 of expander legs 160. Thus, by moving shaft 170 proximally relative to expander legs 160, camming surfaces 188 engage camming edges 190 to bias expander legs 160 apart.

In order to inhibit longitudinal movement of valve installation assembly 142 relative to ring installation assembly 144, barrel halves 158a and 158b are provided with a circumferential flange 192 which is configured to releasably engage a lip 194 formed on an inner surface of housing halves 146a and 146b.

The various motions of single shot tool 140, without an artificial heart valve or heart valve ring installed thereon, will now be described. As shown in Fig. 29, proximal movement of knob 168 draws shaft 170 and thus blade 172 proximally relative to expander legs 160. As blade 172 is drawn proximally, camming surfaces 188 engage camming edges 190 of expander legs 160 thereby spreading camming legs 160 apart. Further, distal advancement of housing 146 relative to barrel 158 causes lip 194 to disengage from flange 192 freeing valve installation assembly 142 for relative movement relative to ring installation assembly 142.

The method of using the second embodiment of the heart valve installation system including single shot tool 140 to install an expandable heart valve ring 12 and a heart valve 70 within a heart H will now be described. Access to heart H is accomplished in a manner similar to that described hereinabove including the use of a retractor R to maintain access through the thoracic cavity to the heart (Fig. 14).

Referring now to Fig. 30, single shot tool 140 is prepared by installing expandable heart valve ring 12, preferably with graft material 130 thereabout, on ring installation assembly 144. A synthetic replacement valve 70, is installed on valve installation assembly 142 without the use of a separate valve holder. As noted above, valve 70 may be retained on valve installation assembly 142 by means of friction surface 156.

As shown in Fig. 31, single shot tool 140 is advanced into heart H until expandable heart valve ring 12 is positioned at the space V where the prior natural heart valve had been removed. Ring expander assembly 144 of single shot tool 140 may now be actuated.

Referring now to Fig. 32, as ring installation assembly 144 is actuated in the manner indicated above, blade 172 is drawn proximally relative to expander legs 160. As blade 172 is drawn proximally, camming surfaces 188 engage camming edges 190 on expander legs 160 thereby driving expander legs 160 apart. As expander legs 160 are driven apart, expandable heart valve ring 12, carried within recesses 162, is forced into an expanding condition against the walls of heart H. As noted hereinabove, expandable heart valve ring 12 includes structure for retaining itself in an expanded state.

Referring to Fig. 33, once heart valve ring 12 has been expanded to securely engage the heart, blade 172 may be moved distally relative to expander legs 160 thereby allowing expander legs 160 to resume a relaxed configuration releasing expanded heart valve ring 12 from recesses 162. In preparation for actuation of valve installation assembly 142, single shot tool 140 may be moved distally relative to expanded heart valve ring 12 thereby moving distal ends 164 of expander legs 160 as well as blade 172 distally of the expanded heart valve ring 12.

Referring now to Fig. 34, valve installation assembly 142 may now be moved distally relative to ring installation assembly 144. Specifically, rings 152 on housing 146 are grasped to move housing 146 distally relative to barrel 158. As shown, distal movement of valve installation assembly 142 advances heart valve 70 towards expanded heart valve ring 12.

Referring to Fig. 35, complete distal advancement of valve installation assembly 142 relative to ring installation assembly 144 drives heart valve 170 into

engagement within expanded heart valve ring 12. Teeth 42 (not shown) engage ring 72 of heart valve 70 to secure heart valve 70 to expanded heart valve ring 12.

Referring back to Figs. 34 and 35, after distal advancement of blade 172 and expander legs 160 relative to expanded heart valve ring 12, blade 172 may be rotated approximately 90° so as to position itself between leaflets 74 of heart valve 70 (FIG. 35). Blade 172 is rotated approximately 90° relative to distal ends 164 of expander legs 160 by manipulating ring expander knob 168. As shown in Fig. 36, single shot tool 140 may now be withdrawn through heart valve 70 such that distal ends 164 of expander legs 160 pass through ring 72 and rectangular portion 186 and blade 172 pass between leaflets 74 of heart valve 70 to withdraw single shot tool 140 from the operative site.

Referring to Fig. 37, heart valve 70 may be further secured to expanded heart valve ring 12 in a manner similar to that described above. Specifically, a few of tabs 44 may be folded over ring 72 of heart valve 70 to thereby secure heart valve 70 to the expanded heart valve ring 12.

It will be understood that various modifications may be made to the embodiments disclosed herein. For example, various other structure to manipulate the ring installation assemblies and valve installation assemblies relative to each other may be provided. Further, other means of securing a heart valve to the valve installation assembly and the expandable ring to the ring installation assembly are contemplated. Therefore, the above description should not be construed as limiting but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

WHAT IS CLAIMED IS:

1. A system for installing a heart valve within a patient comprising:

a heart valve ring implantable within the heart of a patient;

a ring installation assembly configured to engage the heart valve ring with the heart, the ring installation assembly including a support for receipt of the heart valve ring; and

a valve installation assembly having a support to releasably support a synthetic heart valve, the heart valve assembly being operable to insert the heart valve within the heart valve ring.

2. The system of Claim 1, wherein the heart valve ring is expandable from a reduced diameter configuration to an increased diameter configuration to engage the heart.

3. The system of Claim 2, wherein the ring installation assembly is operable to move the heart valve ring from the reduced diameter configuration to the increased diameter configuration.

4. The system of Claim 2, wherein the heart valve ring is formed from an elongated strip of material and includes at least one latch which engages at least one opening formed in the strip to maintain the heart valve ring in the expanded configuration.

5. The system of Claim 1, wherein the heart valve ring includes tabs which are foldable about the heart valve to secure the heart valve to the heart valve ring.

6. The system of Claim 2, wherein the ring installation assembly has camming structure for expanding the heart valve ring from the reduced diameter configuration to the increased diameter configuration.

7. The system of Claim 6, wherein movement of at least part of the camming structure distally relative to the heart valve ring moves the heart valve ring from the reduced diameter configuration to the increased diameter configuration.

8. The system of Claim 6, wherein movement of at least part of the camming structure proximally relative to the heart valve ring moves the heart valve ring from the reduced diameter configuration to the increased diameter configuration.

9. The system of Claim 1, wherein the ring installation assembly includes a ring installation tool and the valve installation assembly includes a valve installation tool separate from the ring installation tool.

10. The system of Claim 9, wherein the valve installation tool includes a housing and a valve positioner movably associated with the housing, the valve positioner movable to insert a heart valve releasably held thereon into the heart valve ring.

11. The system of Claim 10, wherein the valve installation tool includes a release mechanism to release the heart valve thereon.

12. The system of Claim 10, wherein the valve installation tool includes structure for holding the heart valve ring stationary relative to at least the housing of the valve installation tool.

13. The system of Claim 12, wherein the housing including distally projecting quick bars configured to engage the heart valve ring.

14. The system of Claim 1, wherein the valve ring installation assembly and the heart valve installation assembly form a single instrument.

15. The system of Claim 14, wherein at least a portion of the ring installation assembly is movably mounted within the heart valve installation assembly.

16. A method of installing a heart valve within a patient comprising the steps of:

providing a system including a ring installation assembly releasably supporting an expandable heart valve ring and a heart valve installation assembly releasably supporting a heart valve;

accessing a site within the heart from which a natural heart valve has been removed;

expanding the heart valve ring into engagement with the heart;

positioning the heart valve within the heart valve ring; and

securing the heart valve to the heart valve ring.

17. The method as recited in Claim 16, wherein the heart valve ring is expanded into engagement with the heart tissue in response to actuation of the ring installation assembly.

18. The method as recited in Claim 16, wherein the heart valve is positioned within the heart valve ring in response to actuation of the heart valve installation assembly.

19. The method as recited in Claim 18, wherein the ring installation assembly is removed from the accessed site prior to the step of actuating the heart valve installation assembly.

20. The method as recited in Claim 16, wherein the heart valve ring is maintained in an expanded condition by structure incorporated into the heart valve ring.

21. The method as recited in Claim 16, wherein the heart valve is positioned within the heart valve ring by engaging a portion of the heart valve installation assembly with the heart valve ring.

22. The method as recited in Claim 16, wherein the heart valve is positioned within the heart valve ring by moving the heart valve installation assembly relative to the ring installation assembly.

23. The method as recited in Claim 16, wherein the heart valve installation assembly is removed form the accessed site prior to the step of securing the heart valve to the heart valve ring.

24. The method as recited in Claim 16, wherein the step of securing including folding tabs provided on the heart valve ring into engagement with the heart valve.

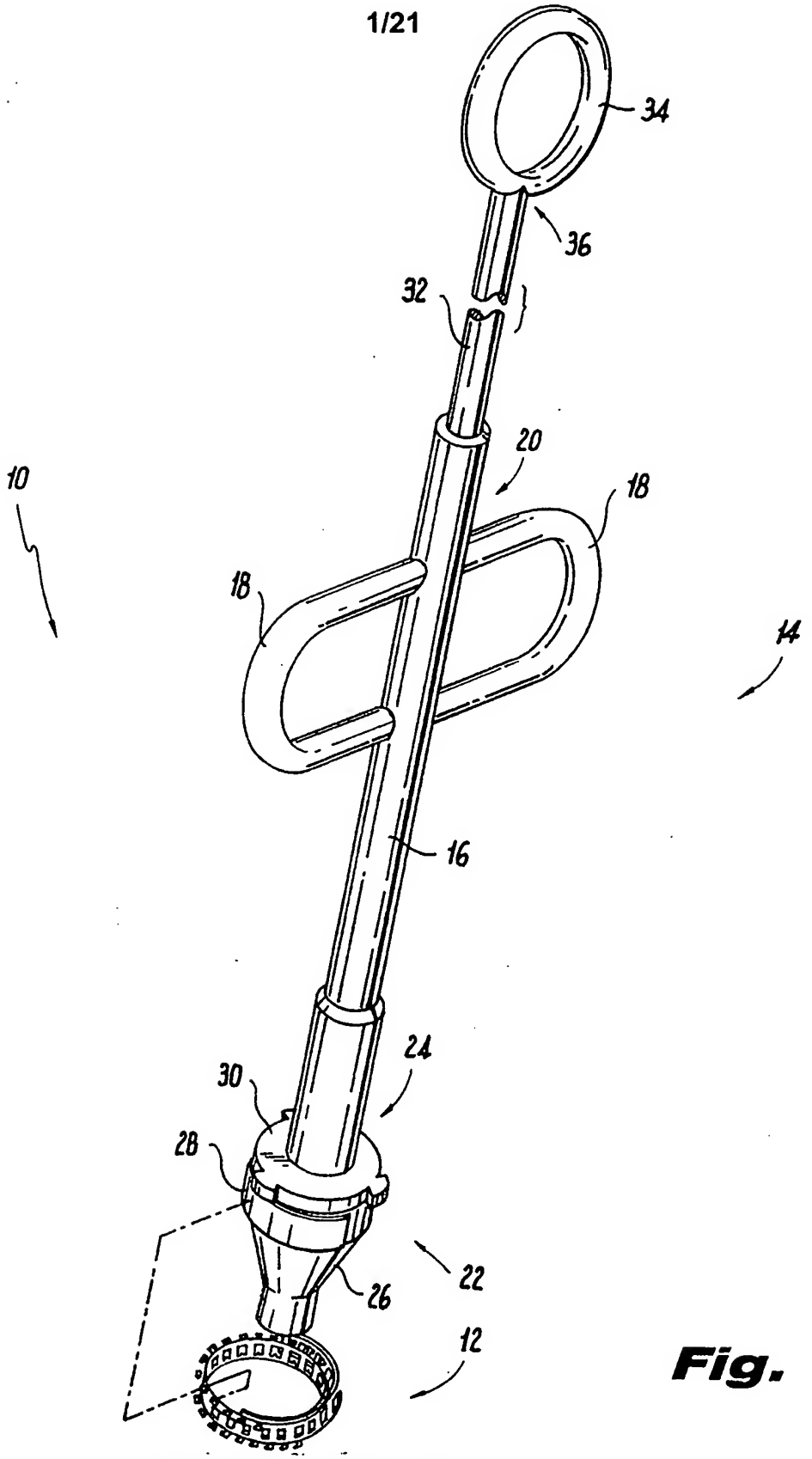


Fig. 1

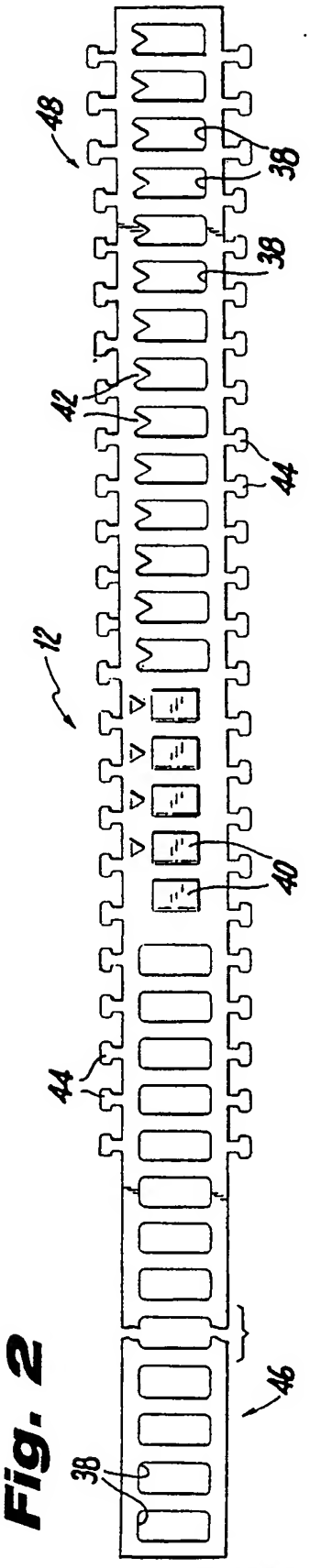


Fig. 2

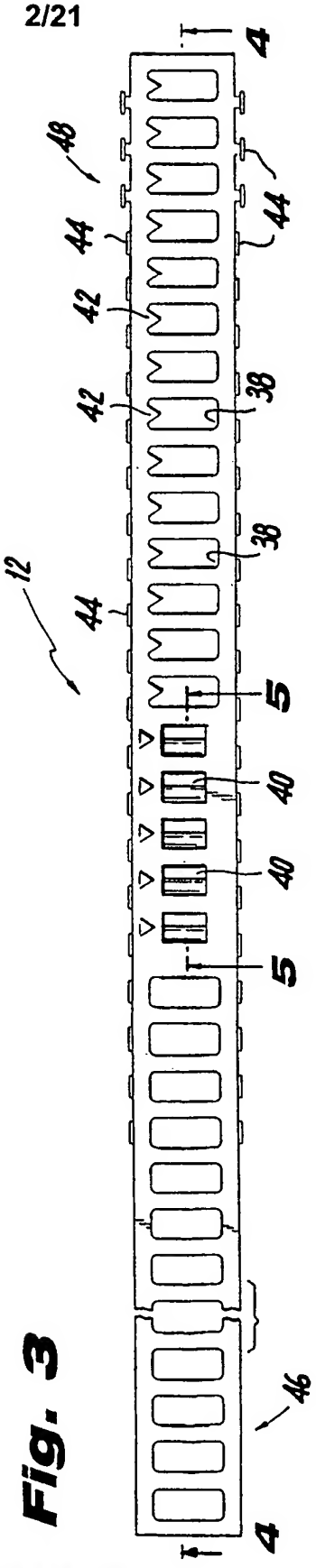


Fig. 3

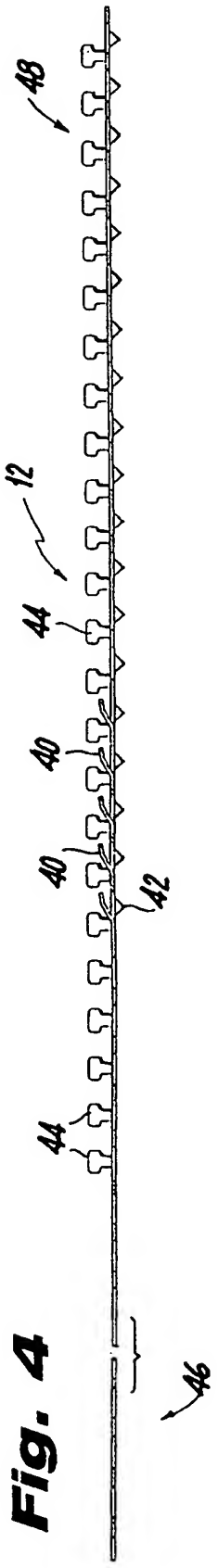


Fig. 4

Fig. 5

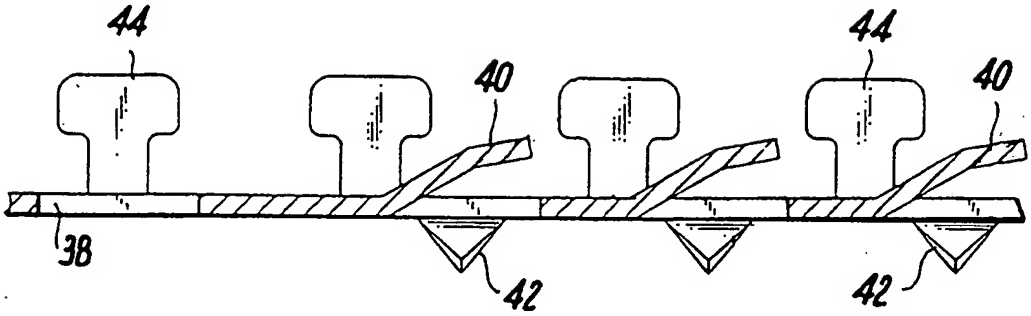
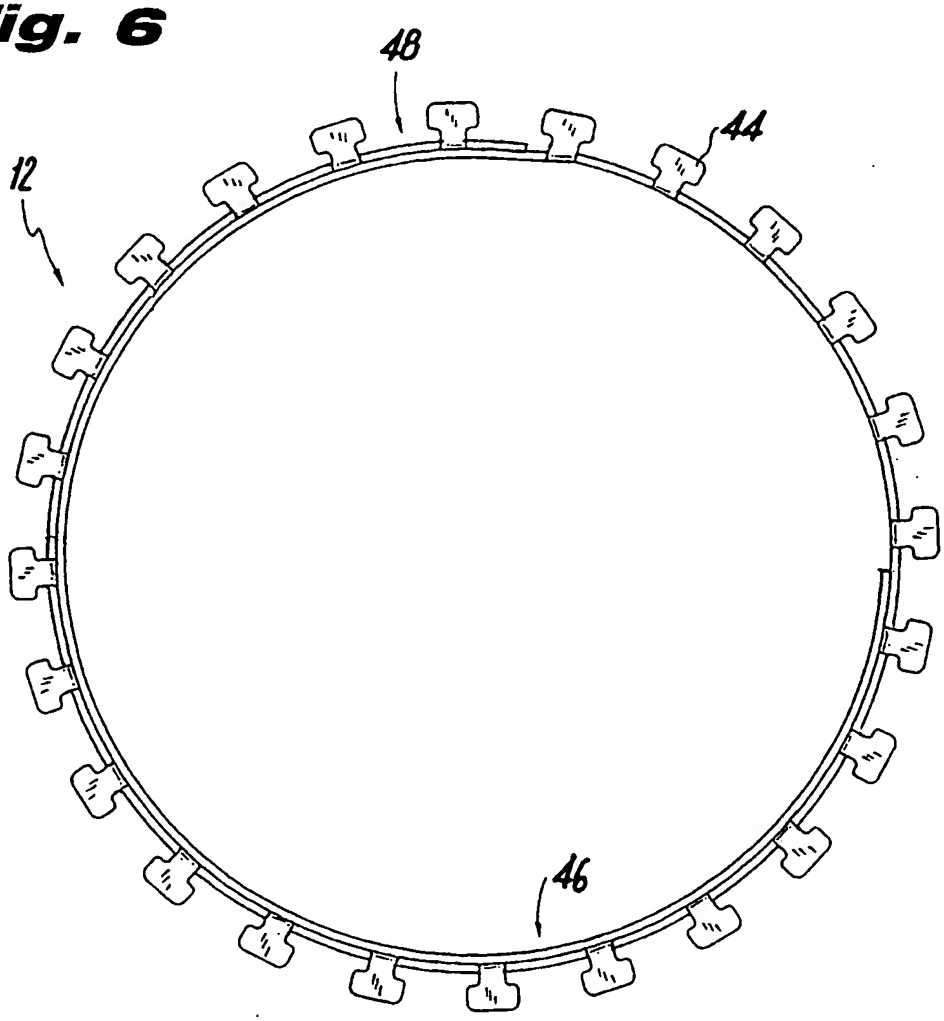
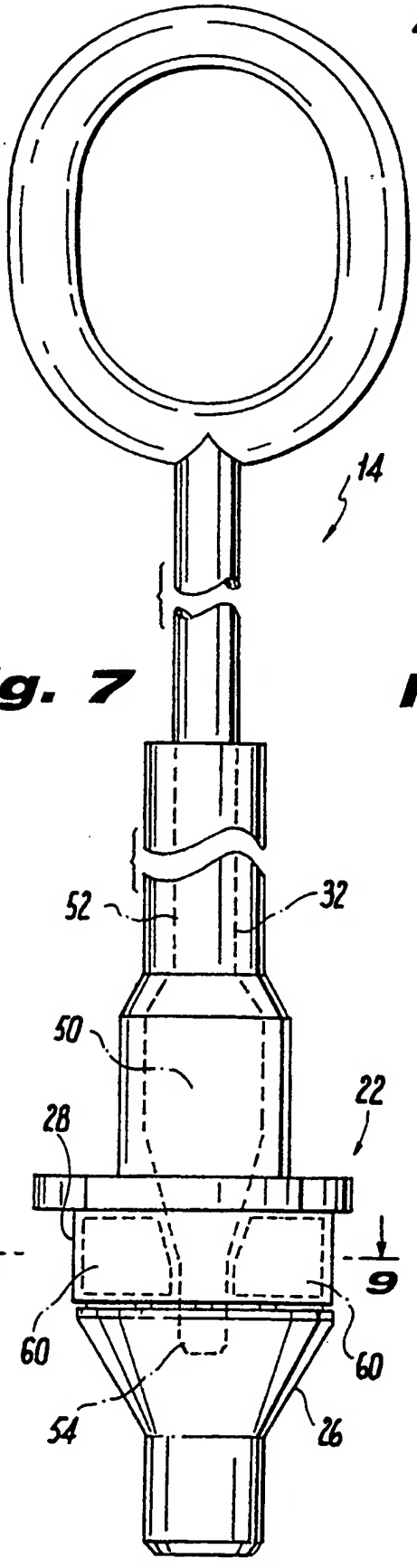


Fig. 6





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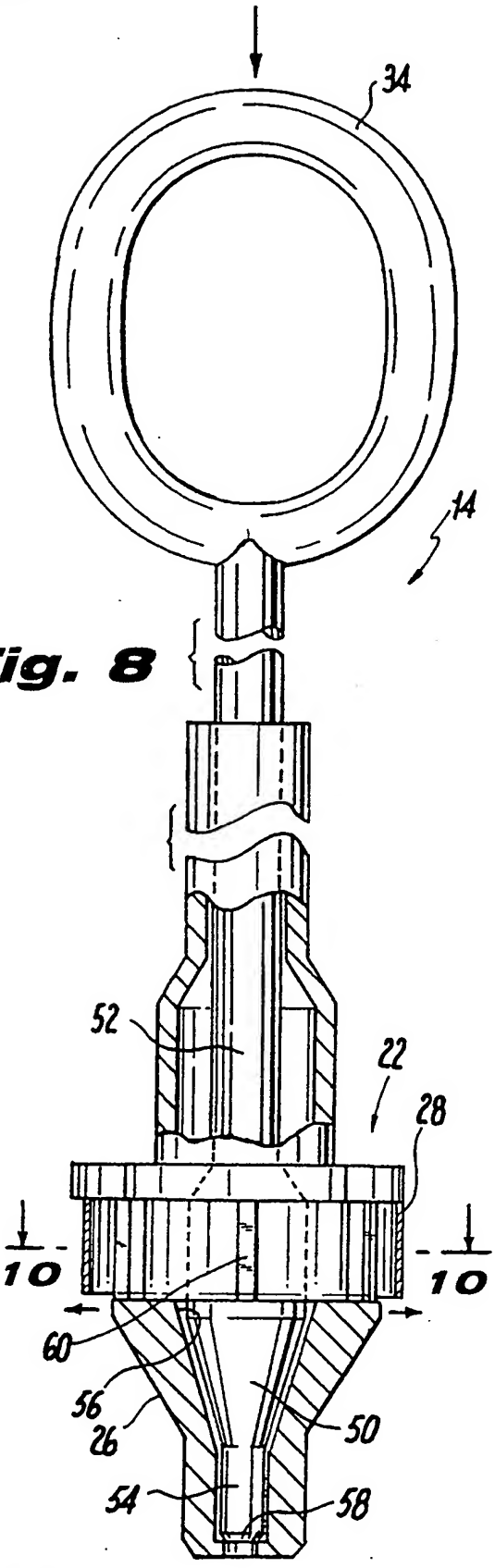


Fig. 8

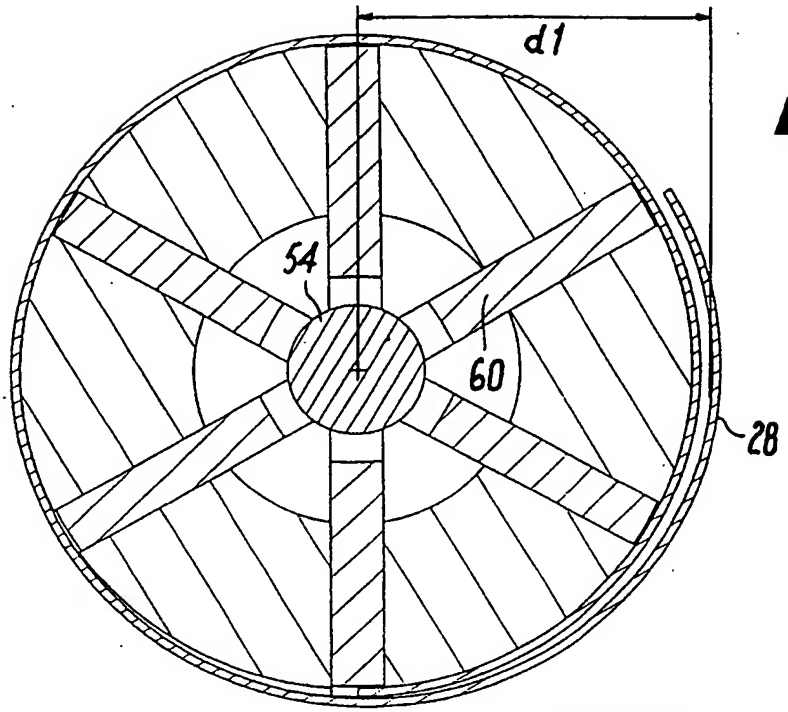


Fig. 9

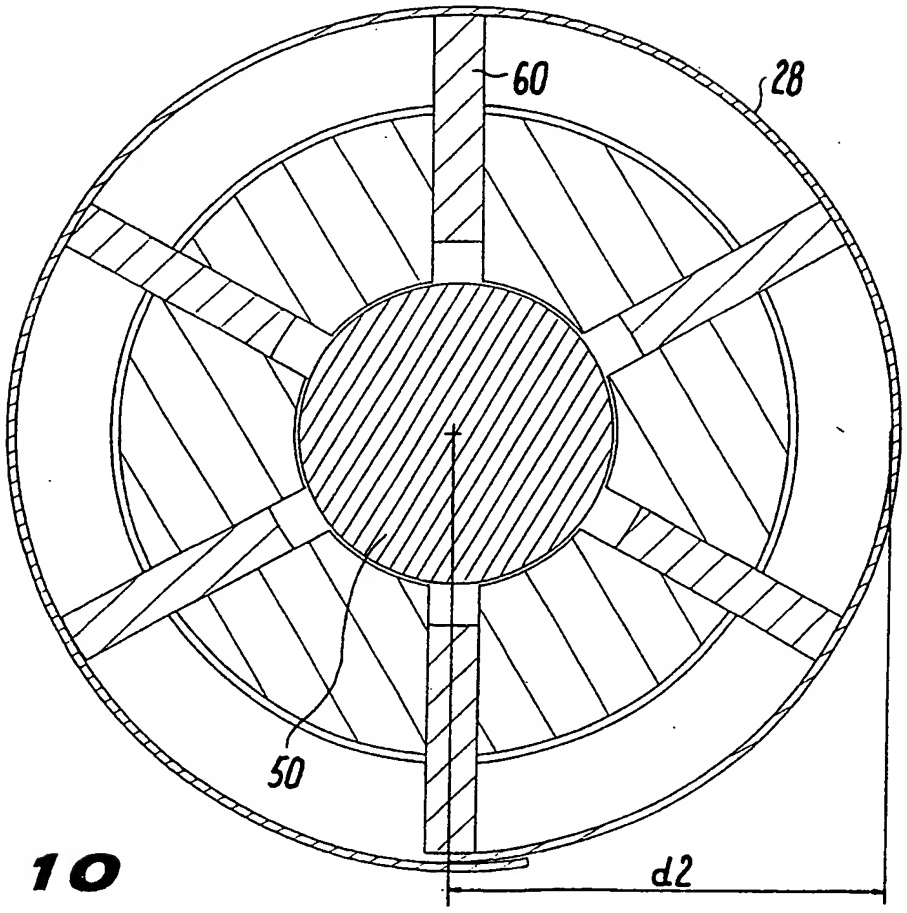
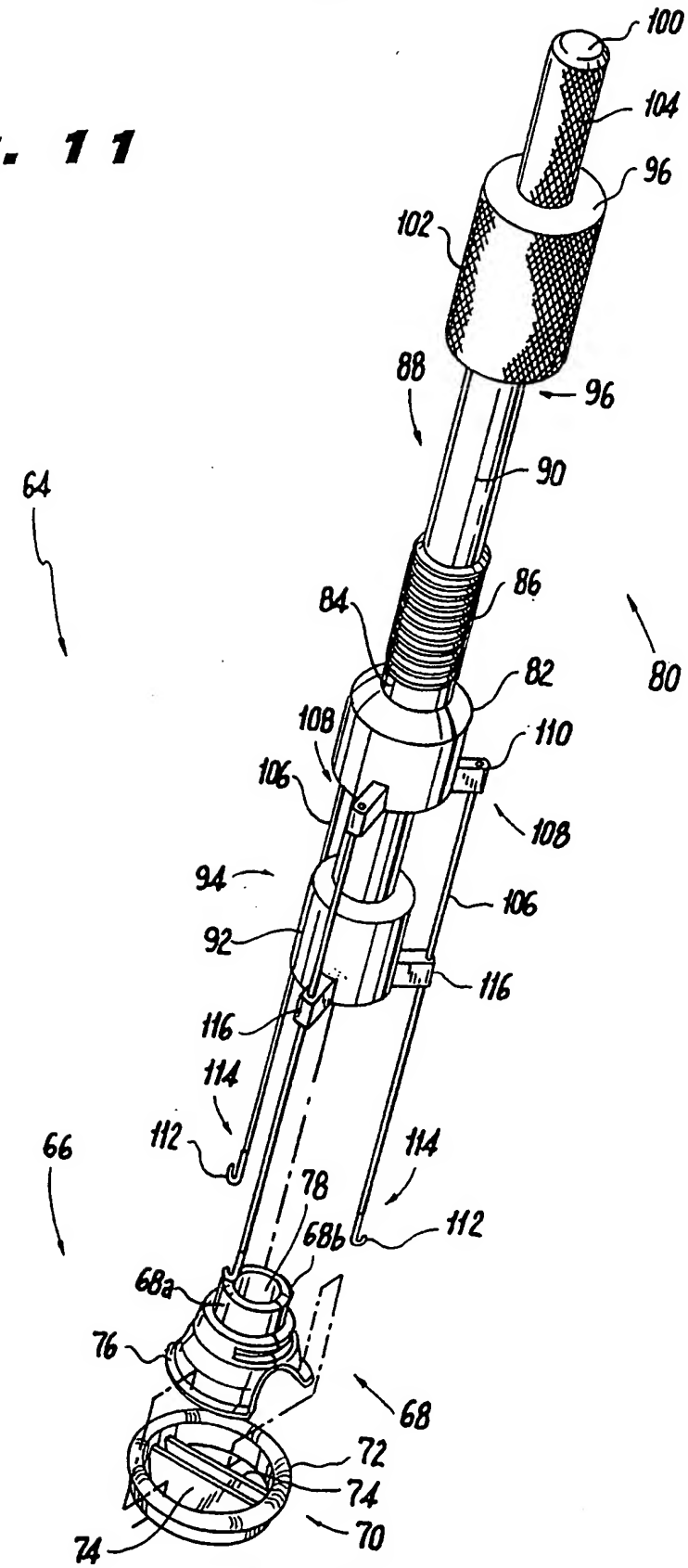


Fig. 10

Fig. 11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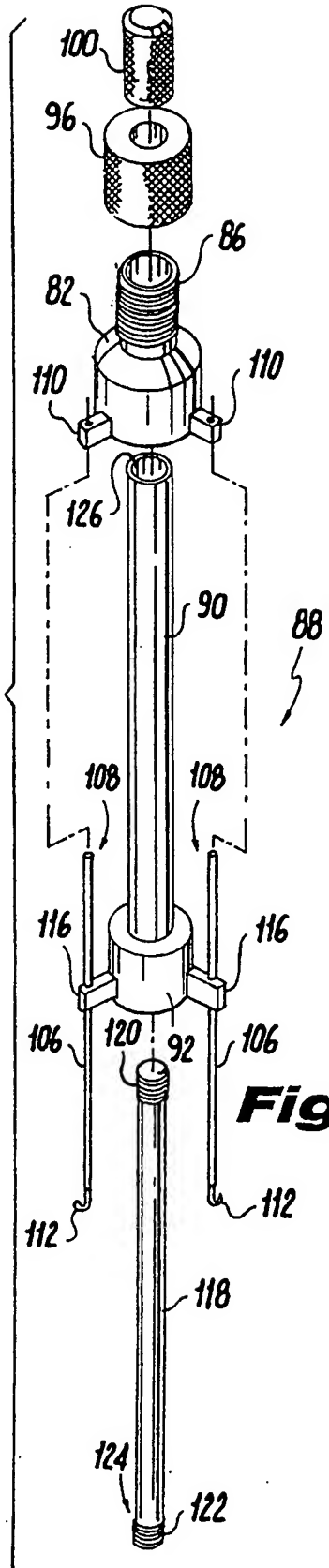
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Fig. 12

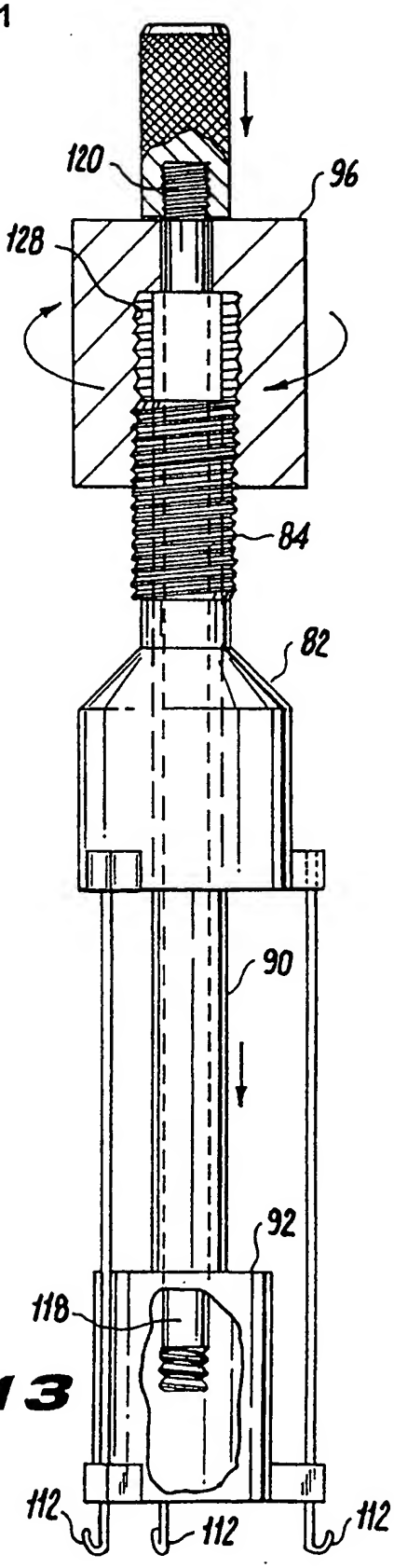
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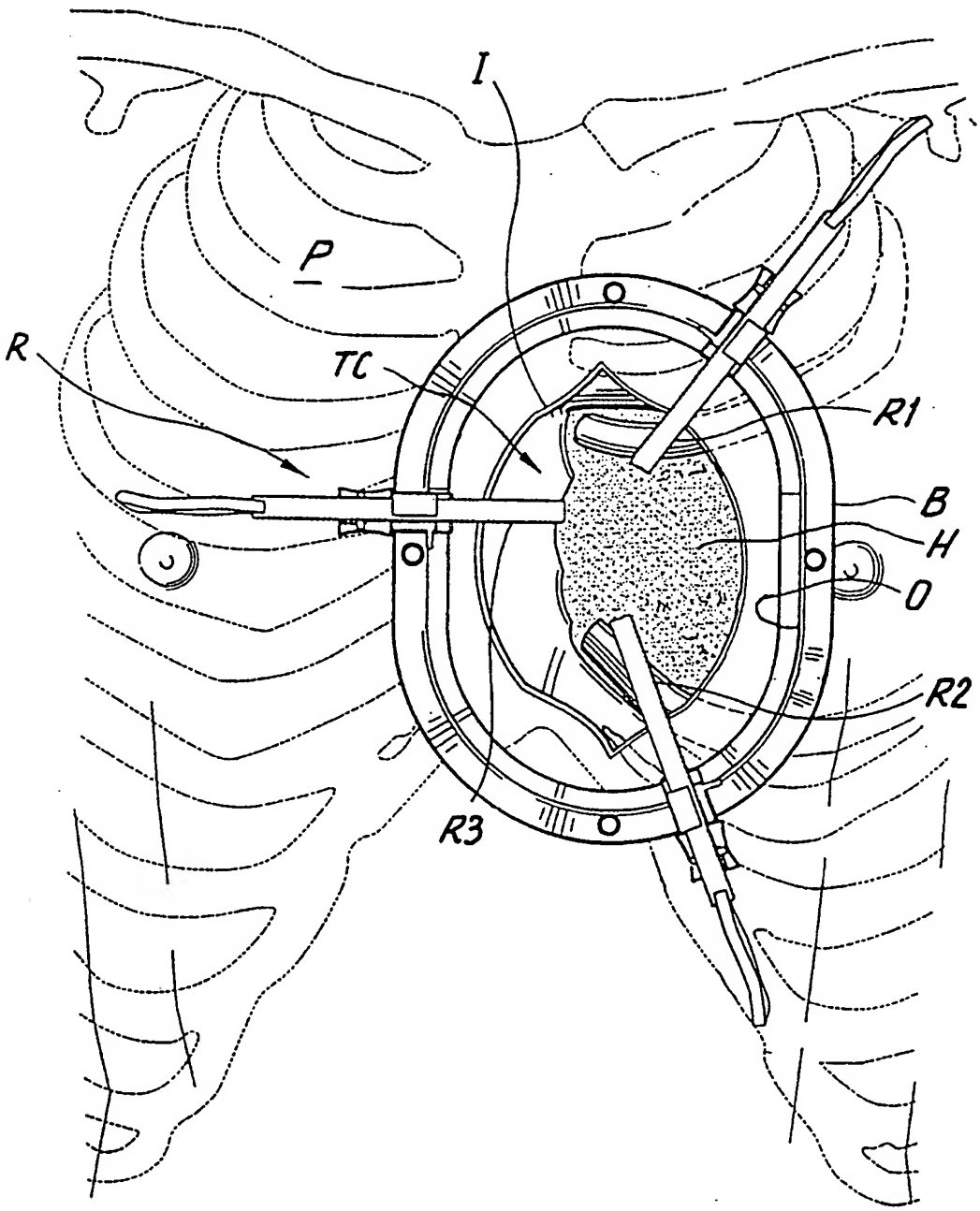
Fig. 13



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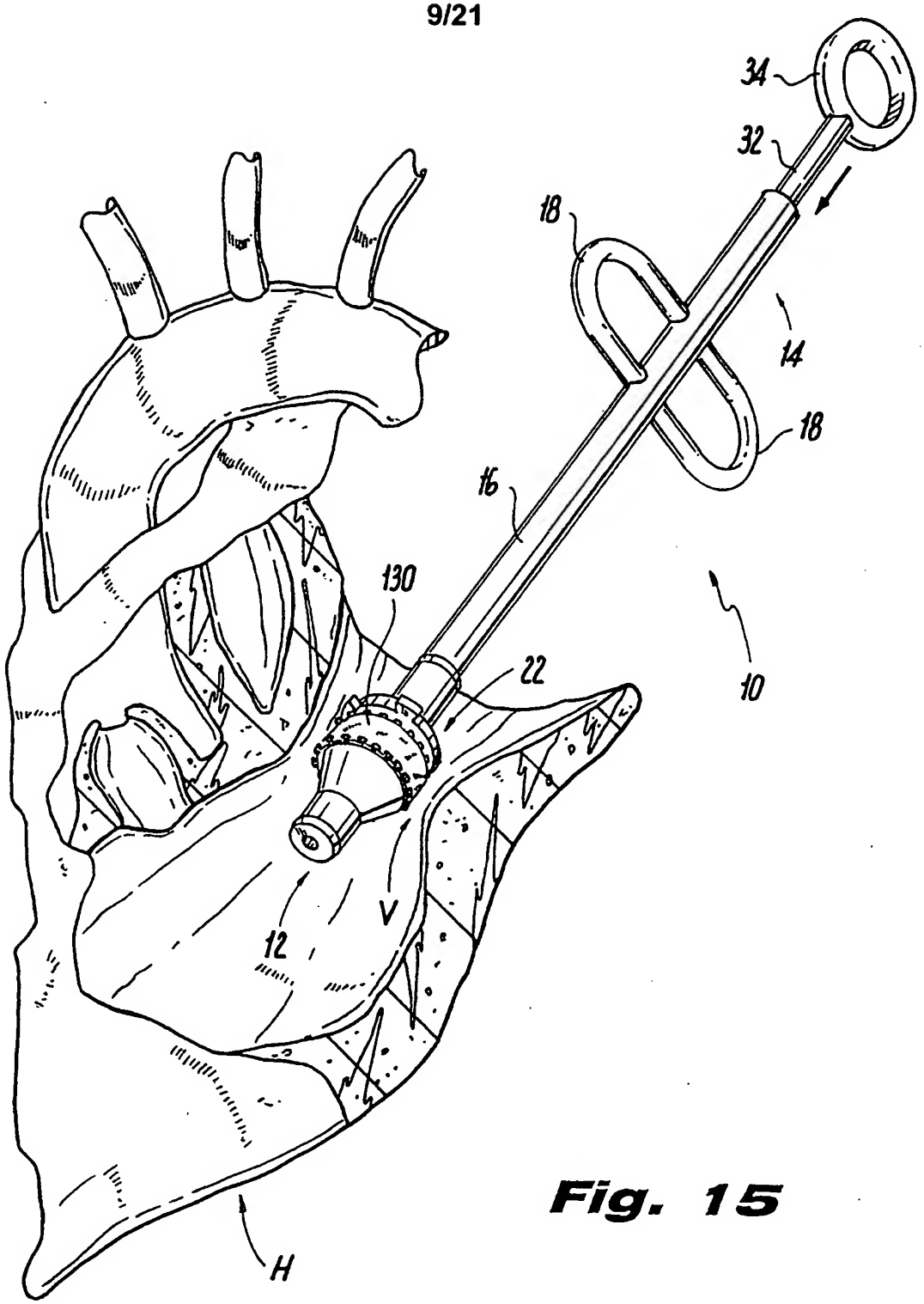
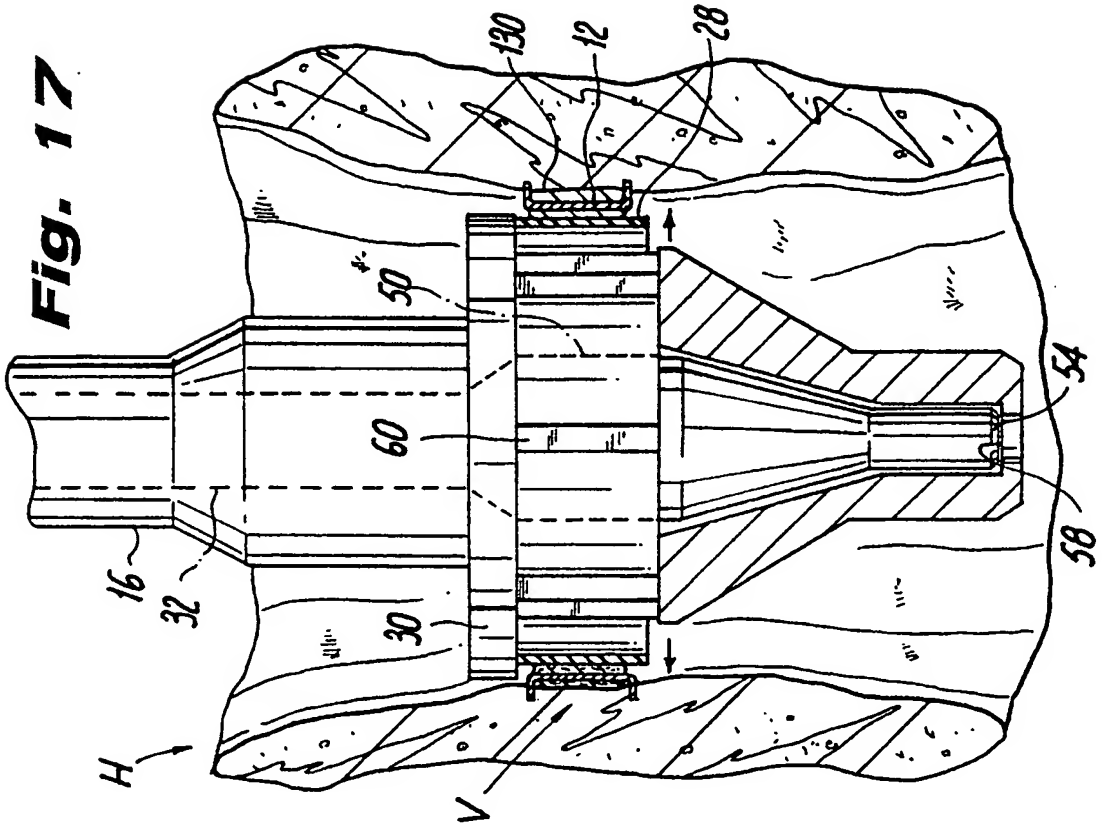


Fig. 15

Fig. 17



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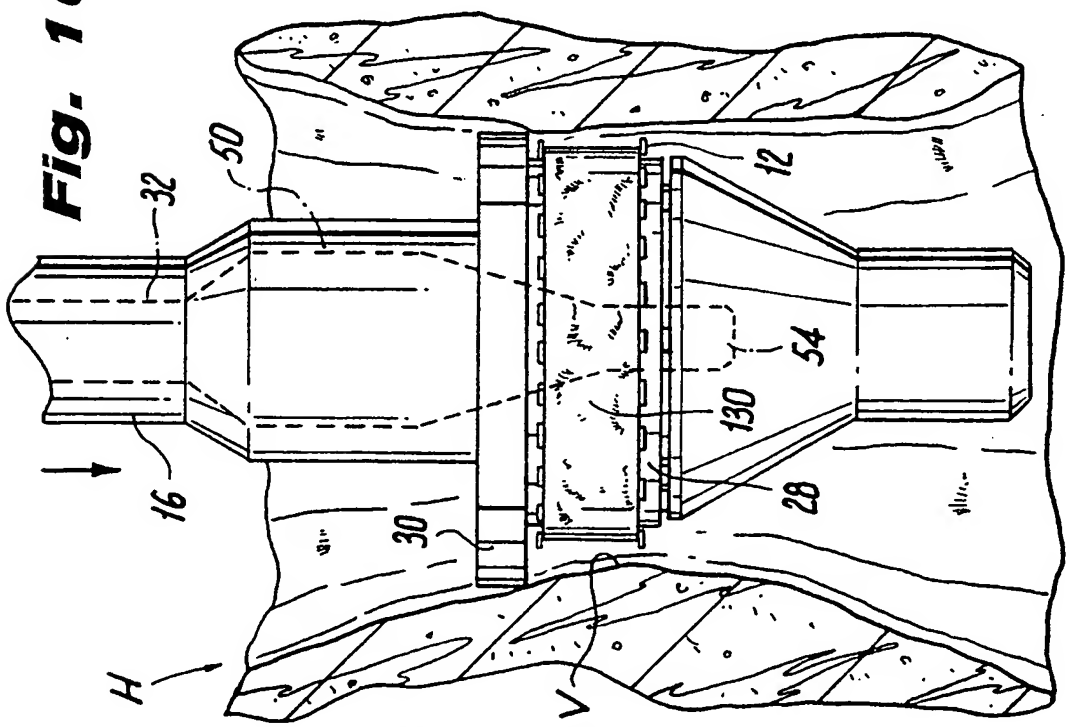

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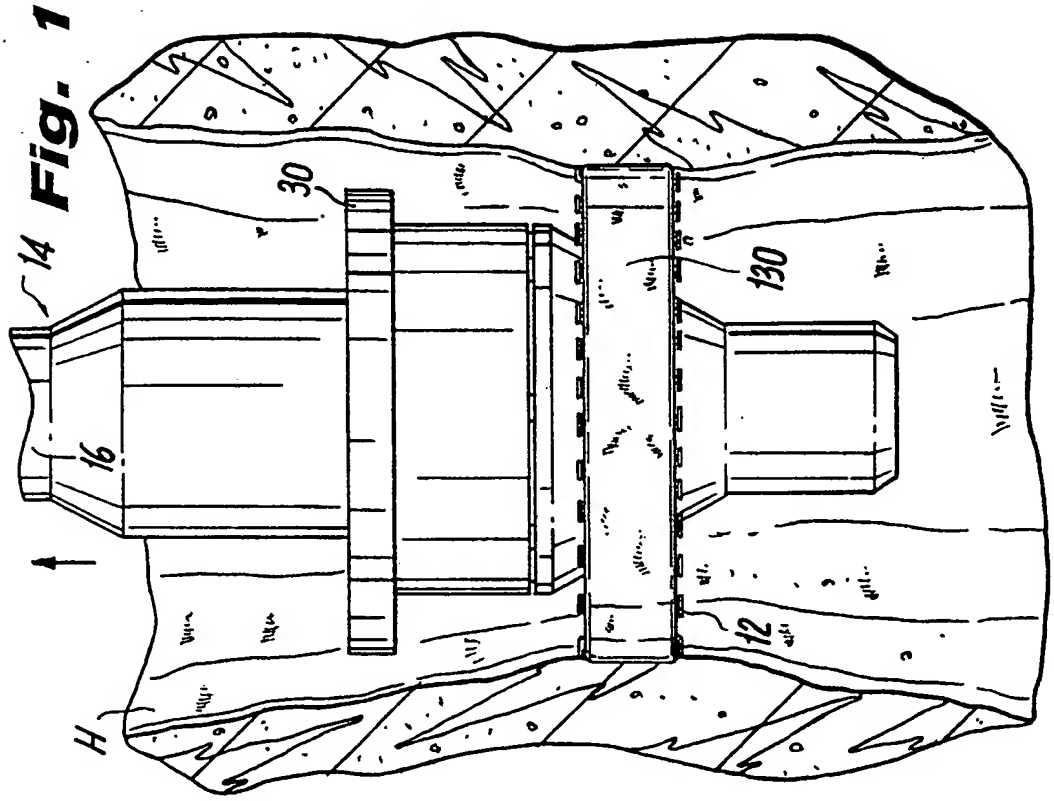

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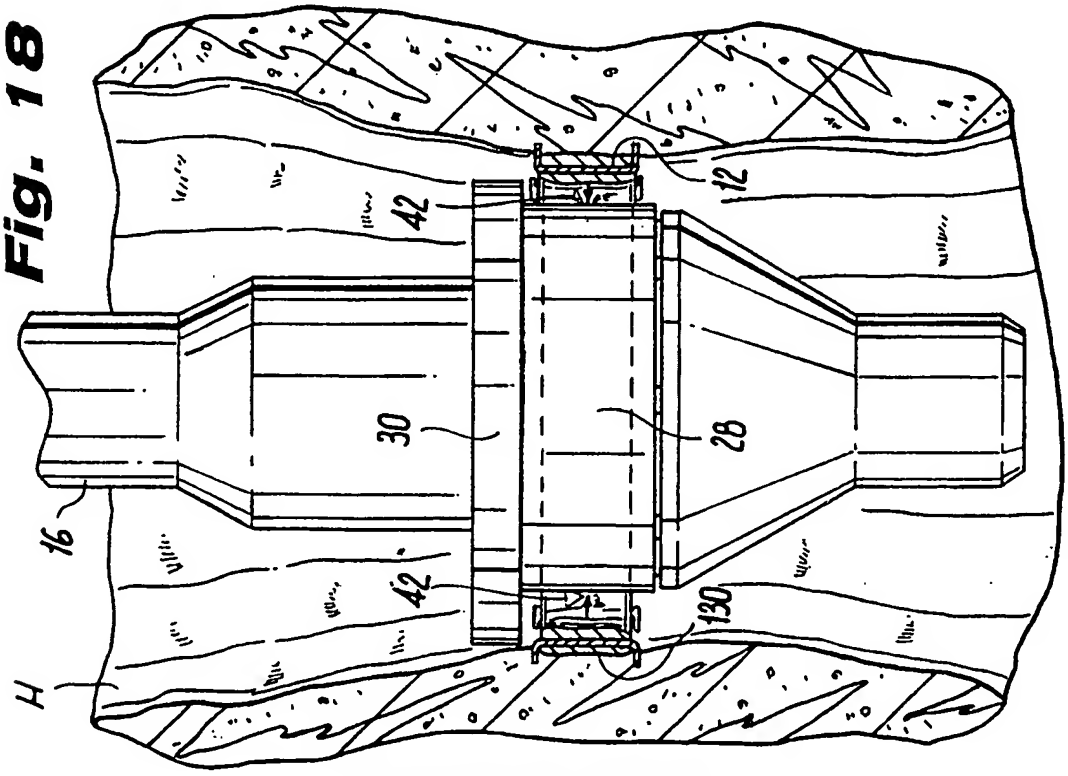

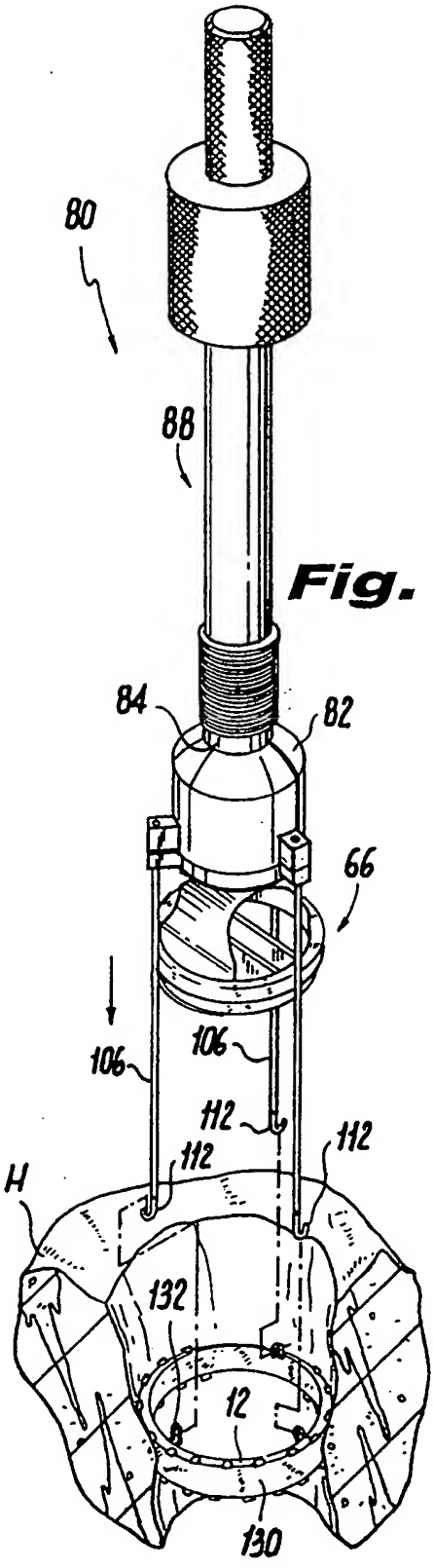
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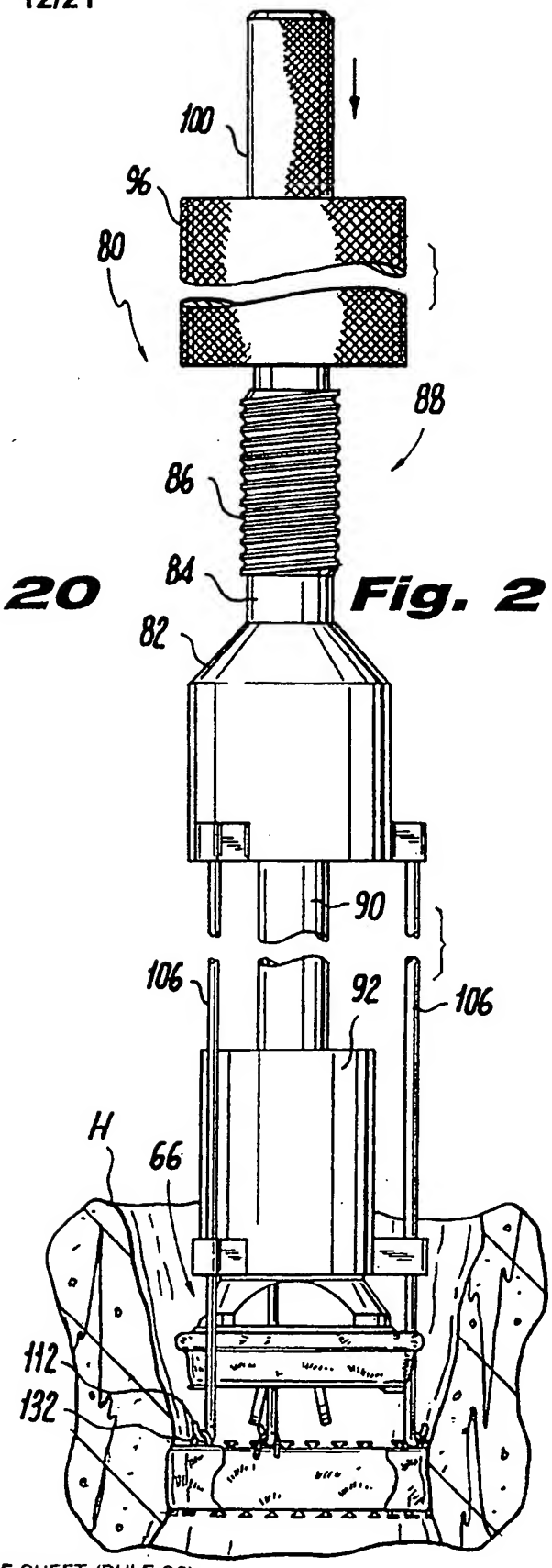
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Fig. 21

Fig. 22

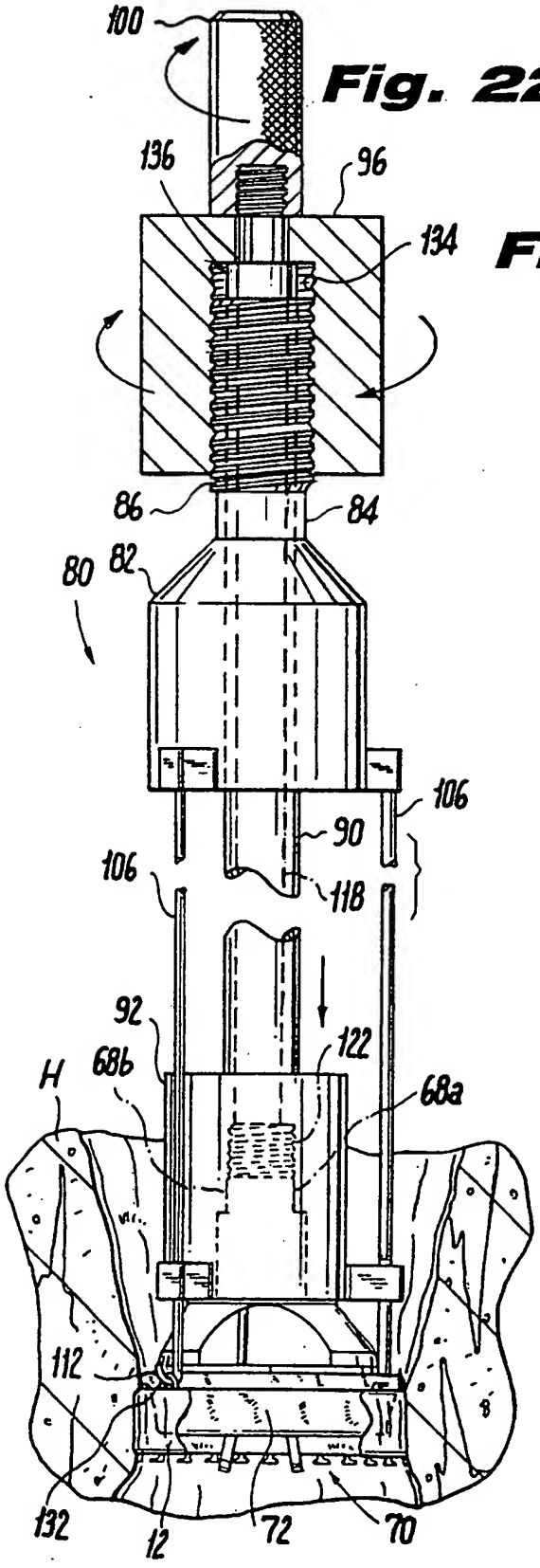
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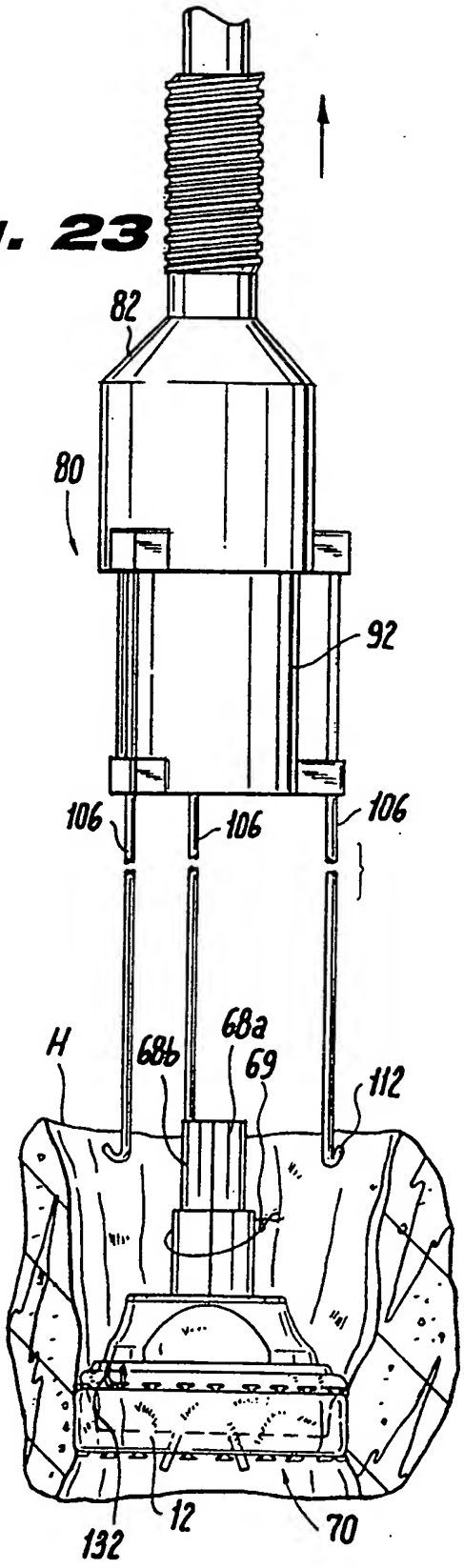
Fig. 23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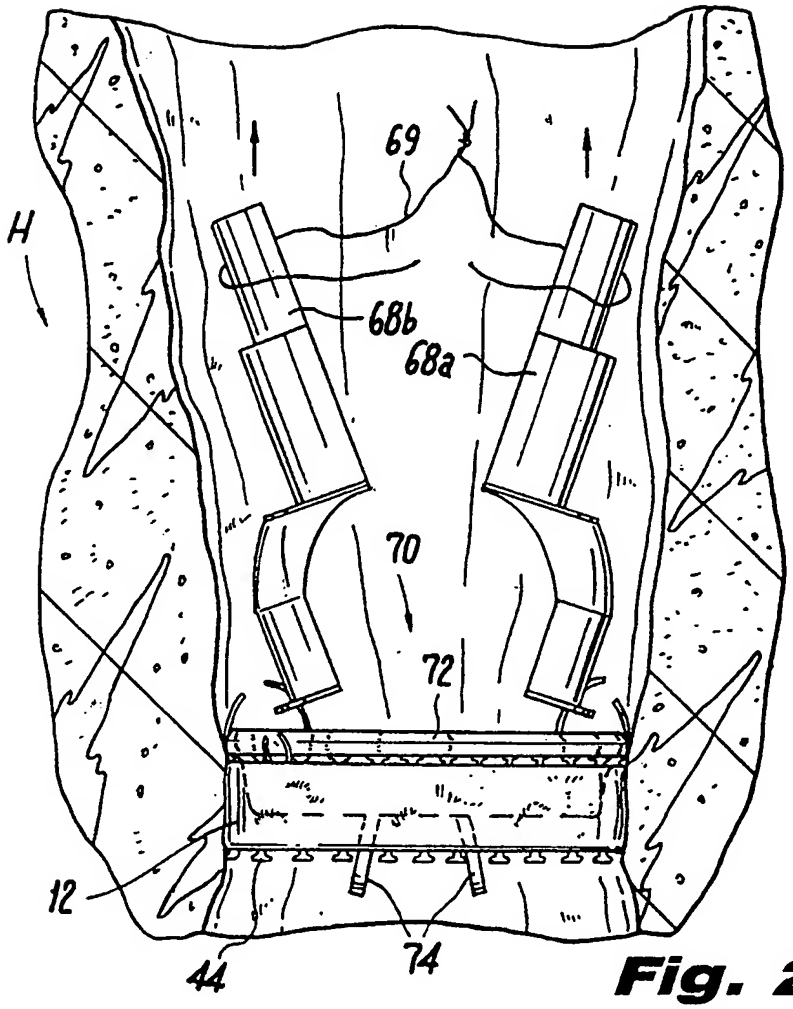

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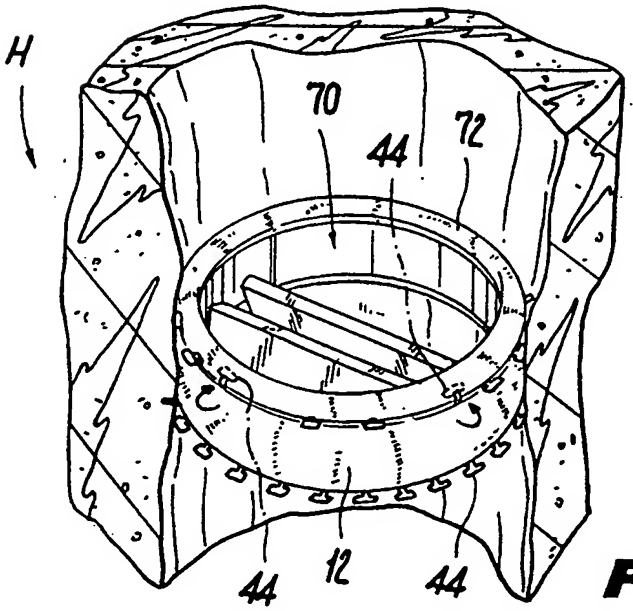
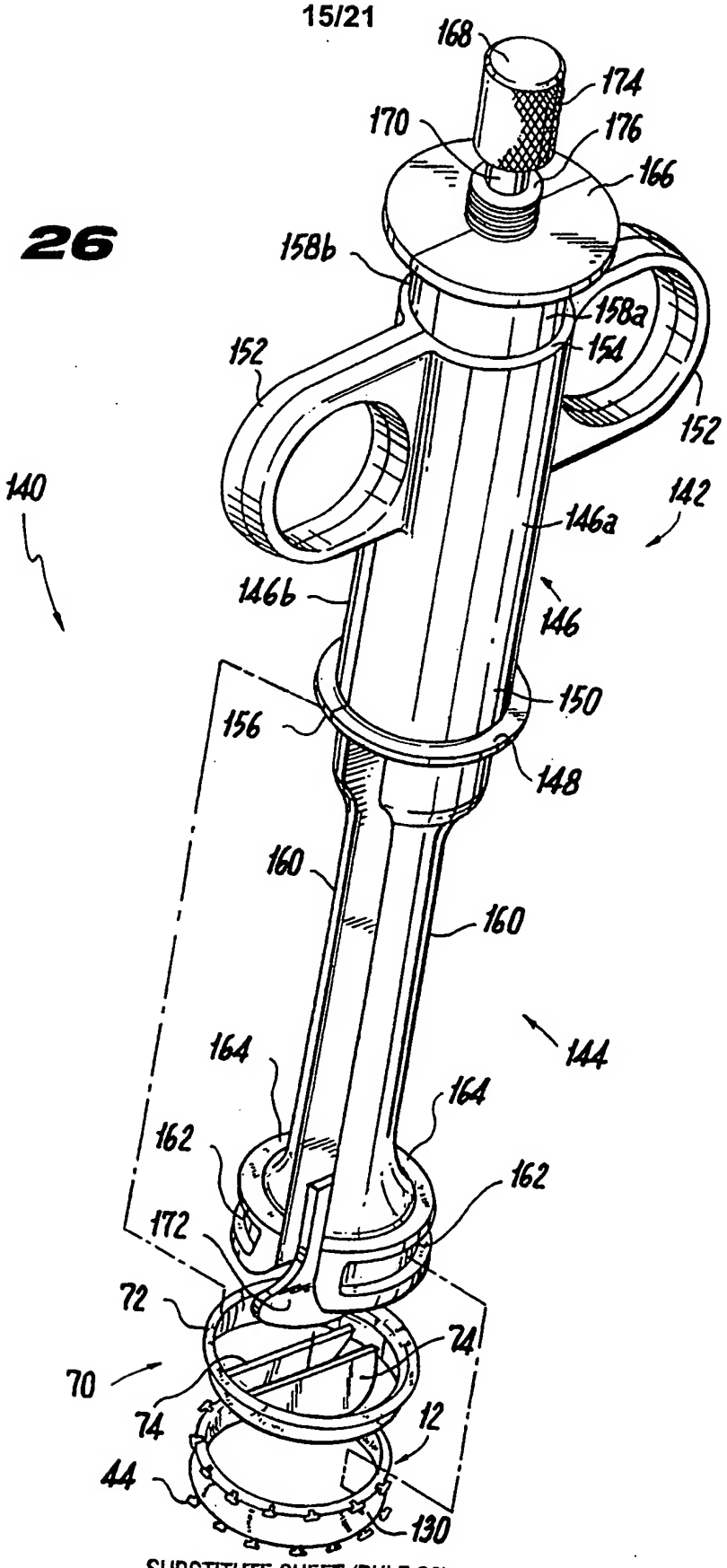


Fig. 25

Fig. 26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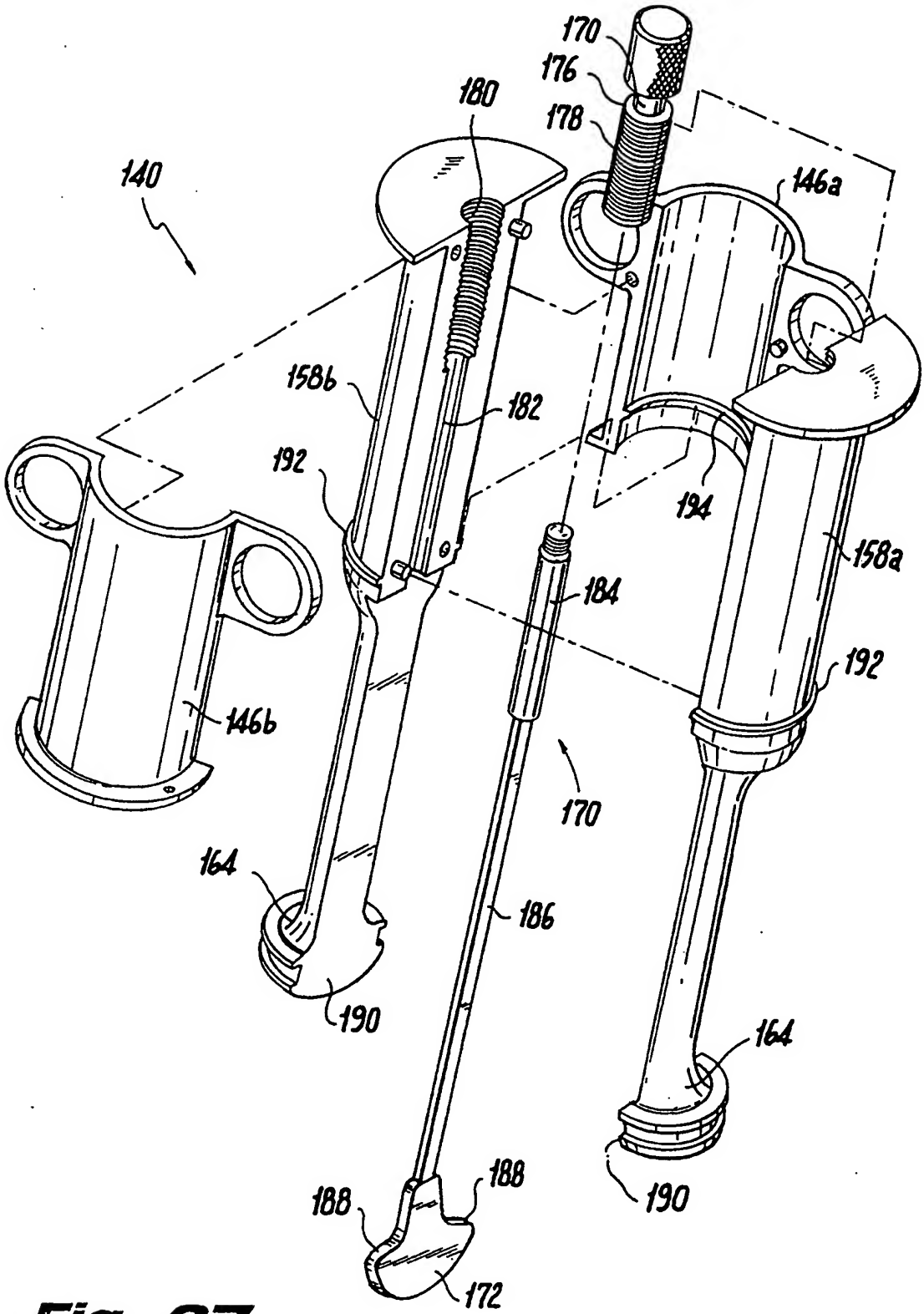
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Fig. 27

Fig. 28

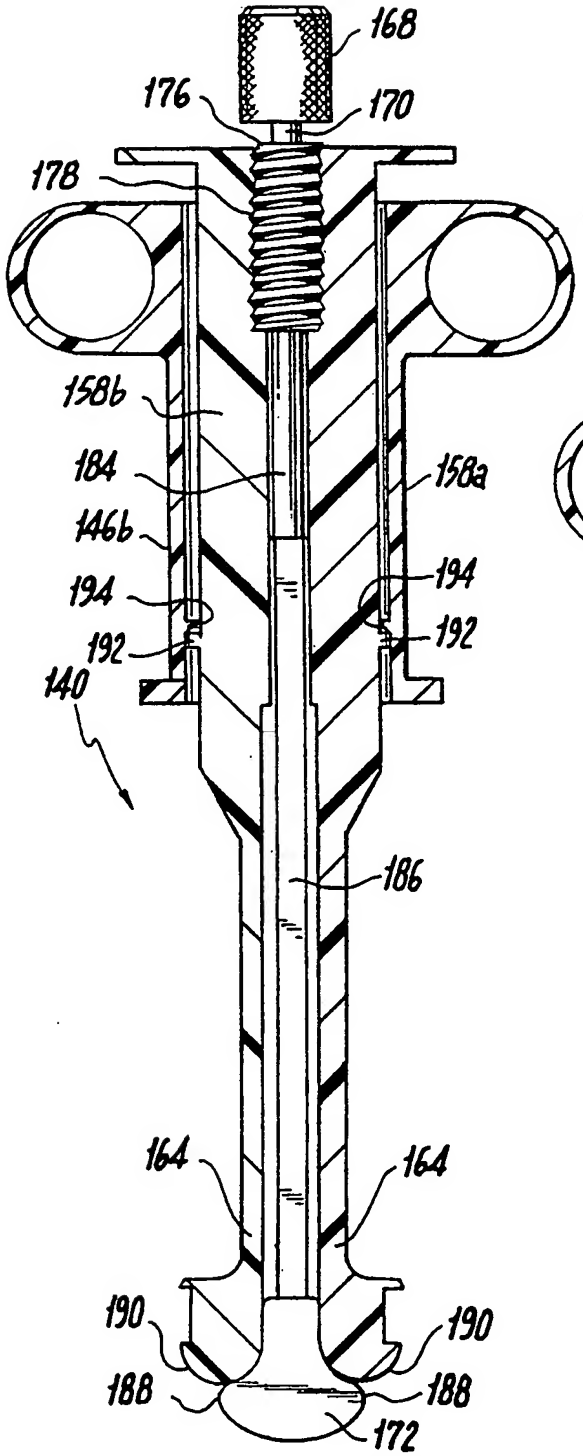
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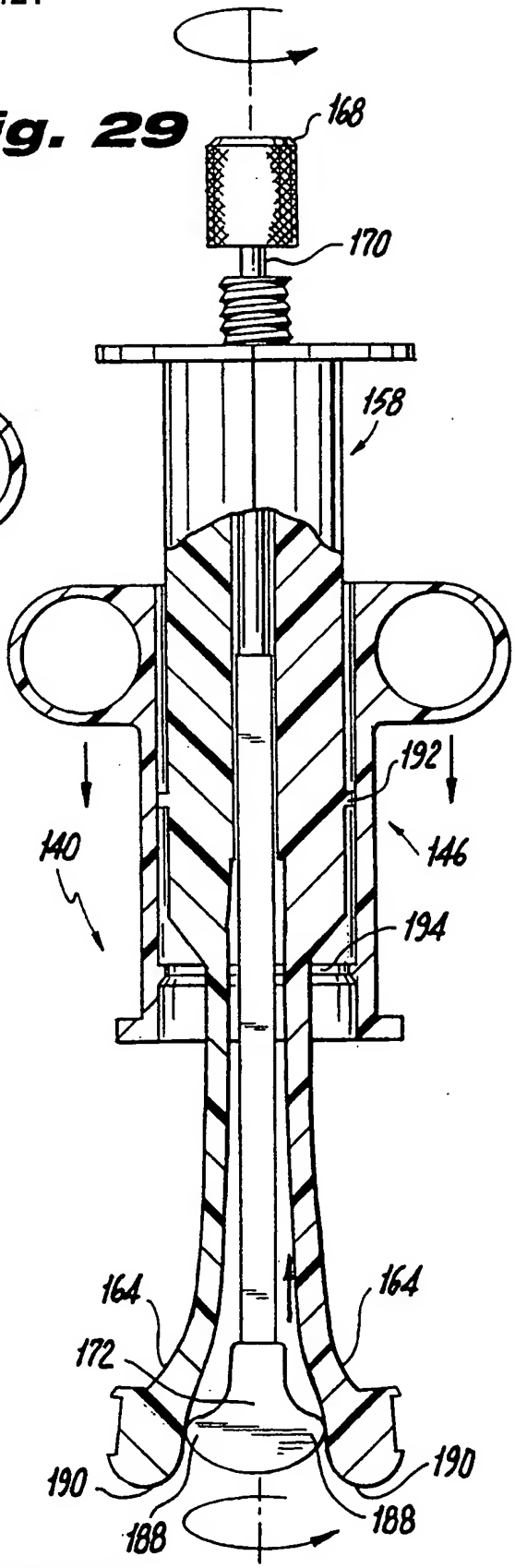
Fig. 29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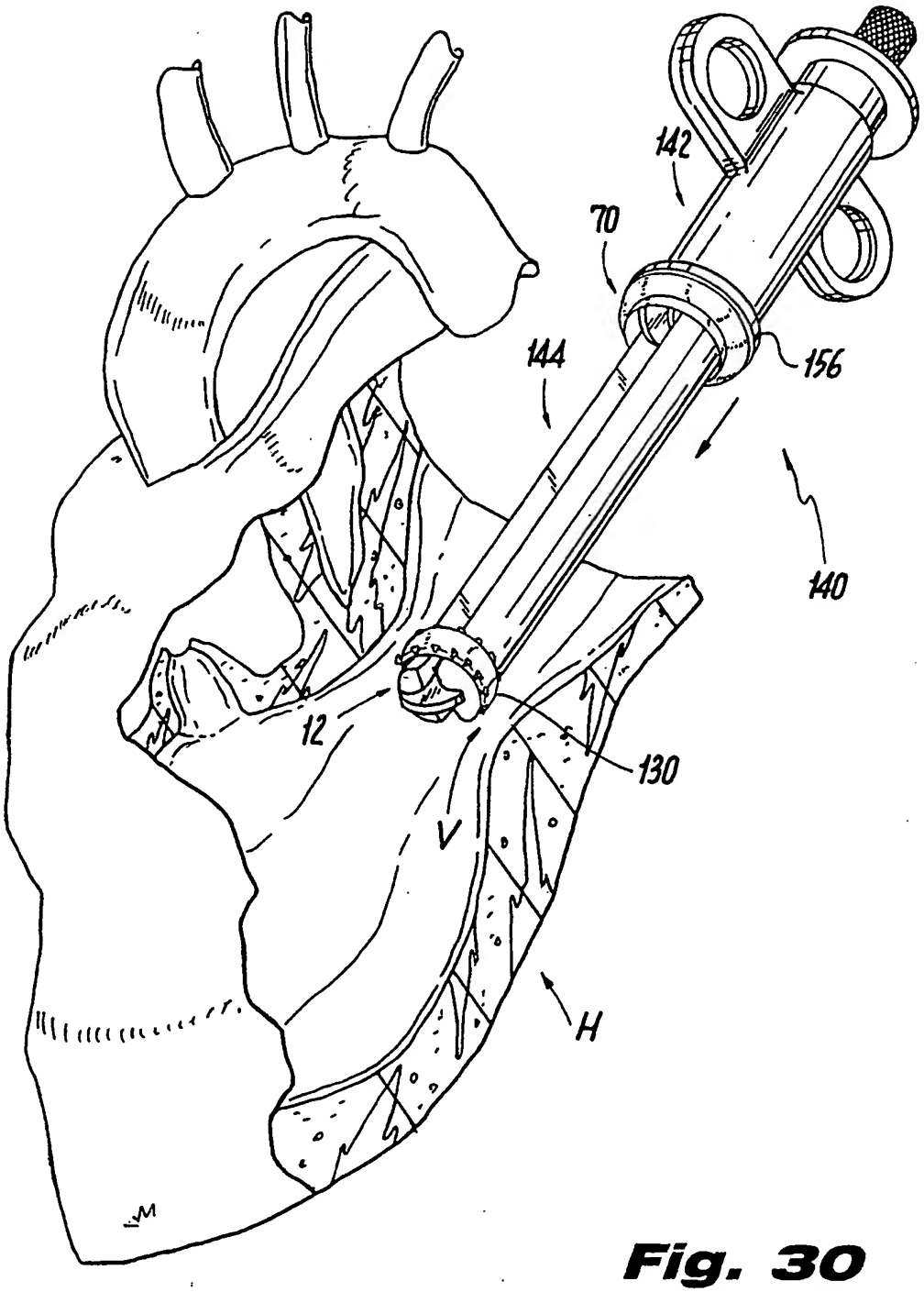


Fig. 30

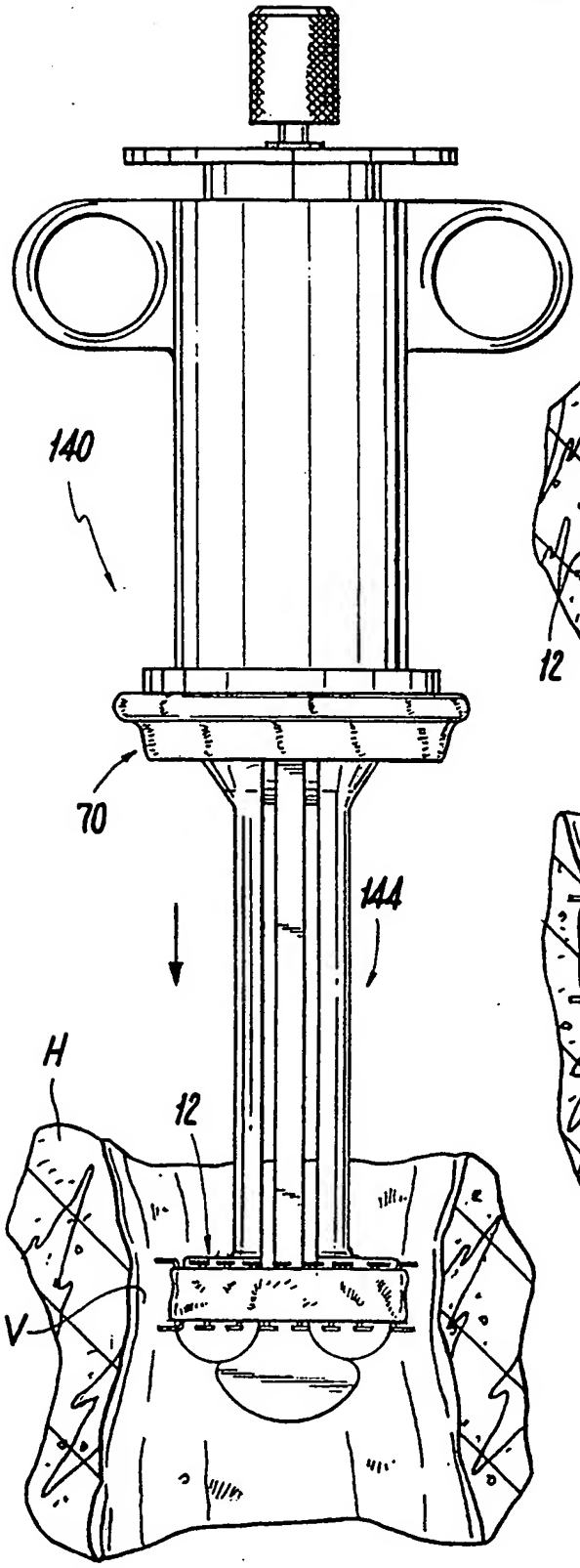
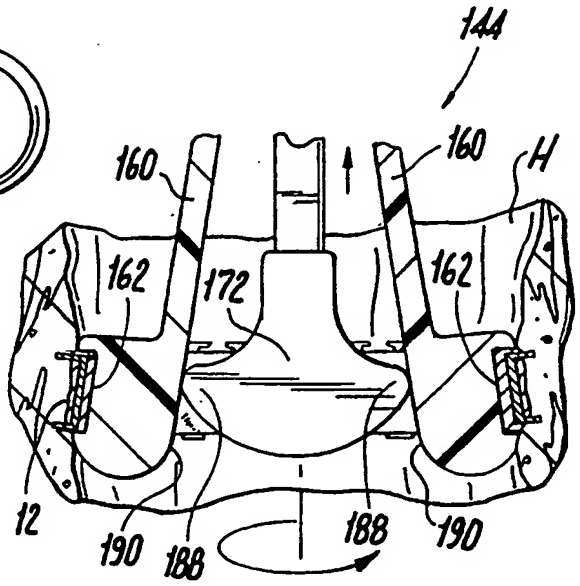


Fig. 31

Fig. 32



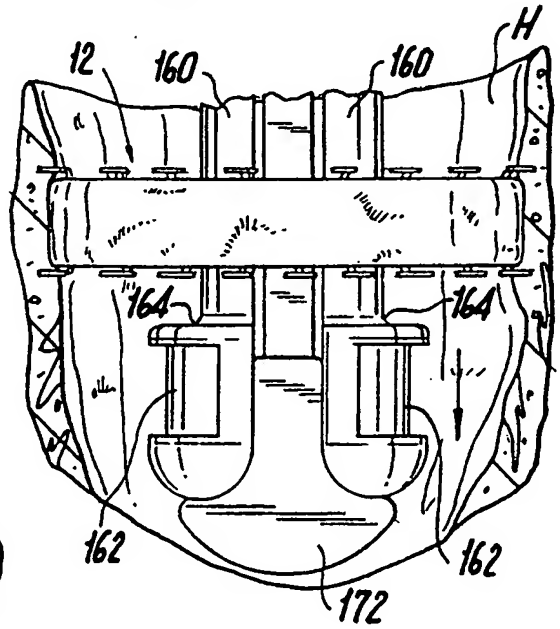
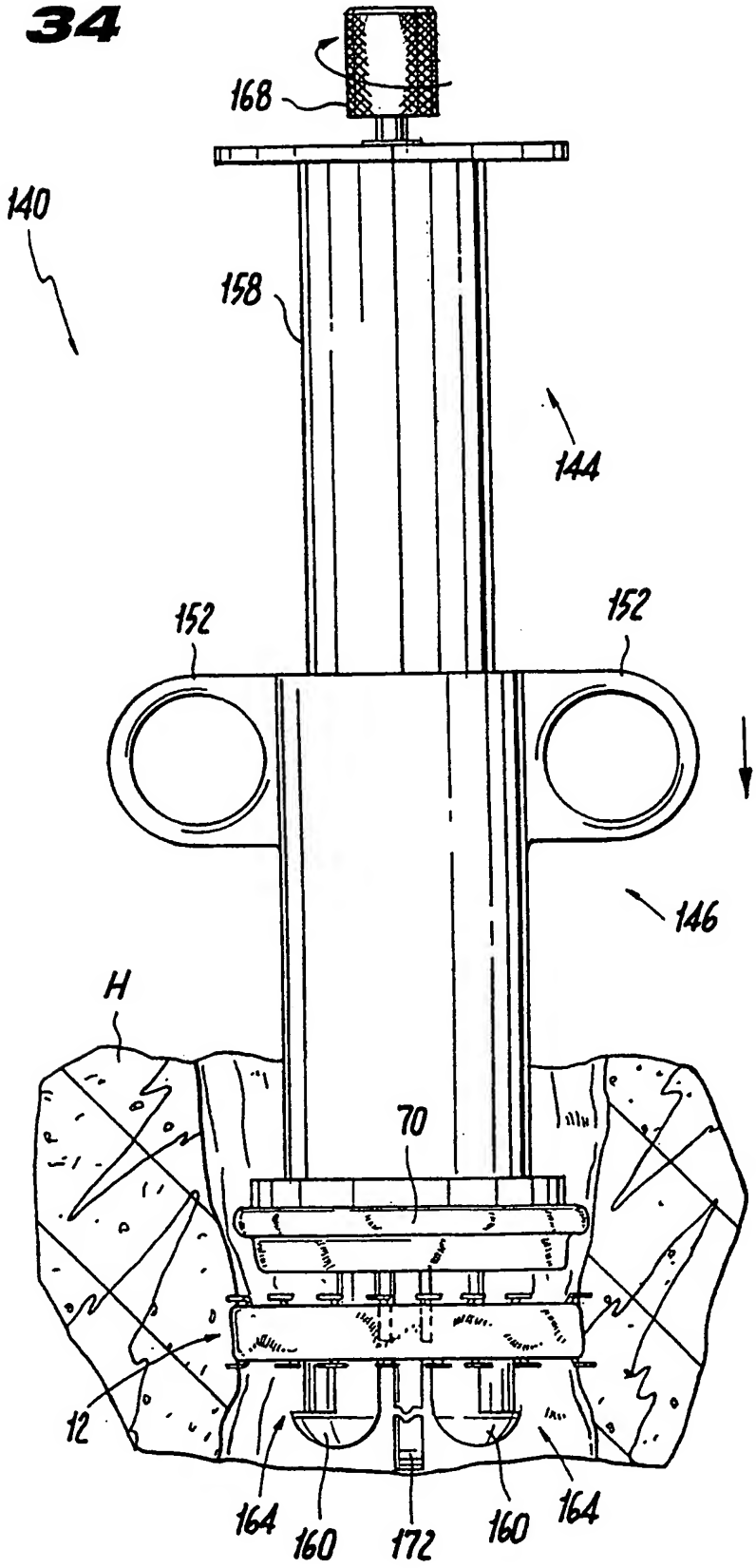


Fig. 33

Fig. 34



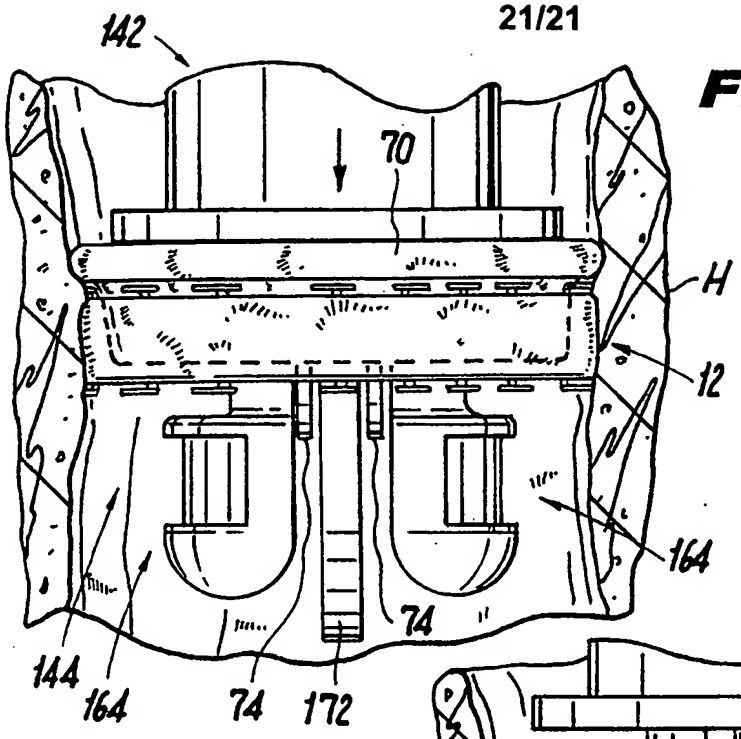


Fig. 35

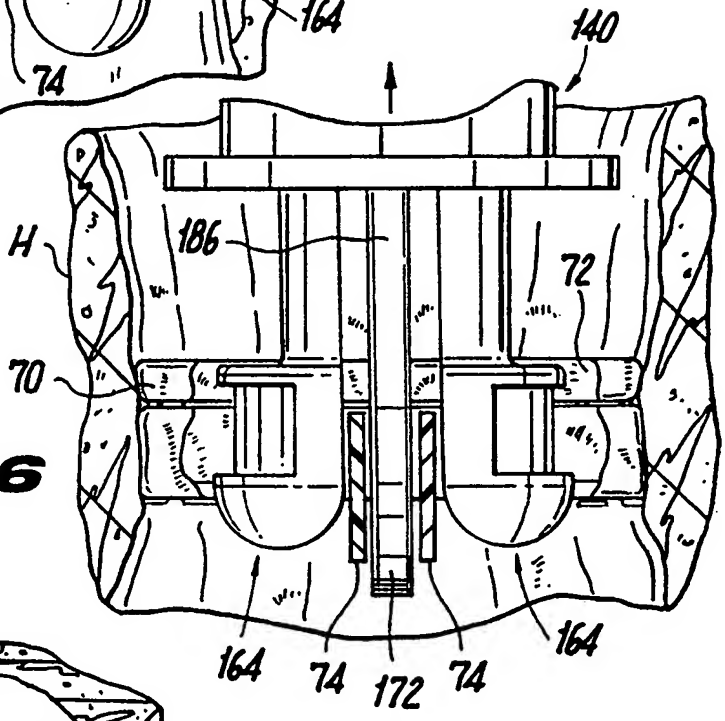


Fig. 36

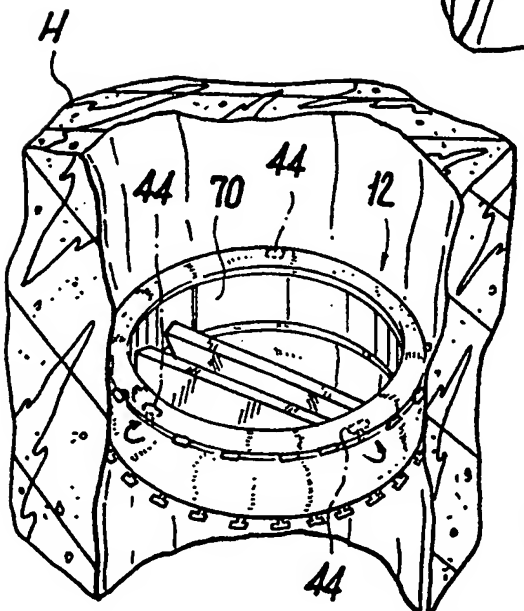


Fig. 37

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/19232

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61F 2/24
US CL :623/2
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 623/2, 900; 294/94, 96; 100

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P --- Y, P	US 5,716,370 A (WILLIAMSON, IV et al.) 10 February 1998 (10.02.98), figures; col. 4, lines 52 and 53; col. 6, lines 45-49; col. 8, lines 48-54; col. 11, lines 41-43; col. 12, line 9 et seq.; col. 13, lines 44-50; col. 14, lines 32-38; and col. 16, lines 23-25 and 39-54.	1-3, 6-11, 16-23 --- 5, 12-15, 24

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 10 NOVEMBER 1998	Date of mailing of the international search report 18 DEC 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer DAVE WILLSE Telephone No. (703) 308-2903

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